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(54) **APPARATUS AND METHODS FOR TREATMENT OF PATELLOFEMORAL CONDITIONS**

(71) Applicant: **Cotera, Inc.**, Menlo Park, CA (US)

(72) Inventors: **Vivek Shenoy**, Redwood City, CA (US); **Hanson S. Gifford, III**, Redwood City, CA (US)

(73) Assignee: **Cotera, Inc.**, Menlo Park, CA (US)

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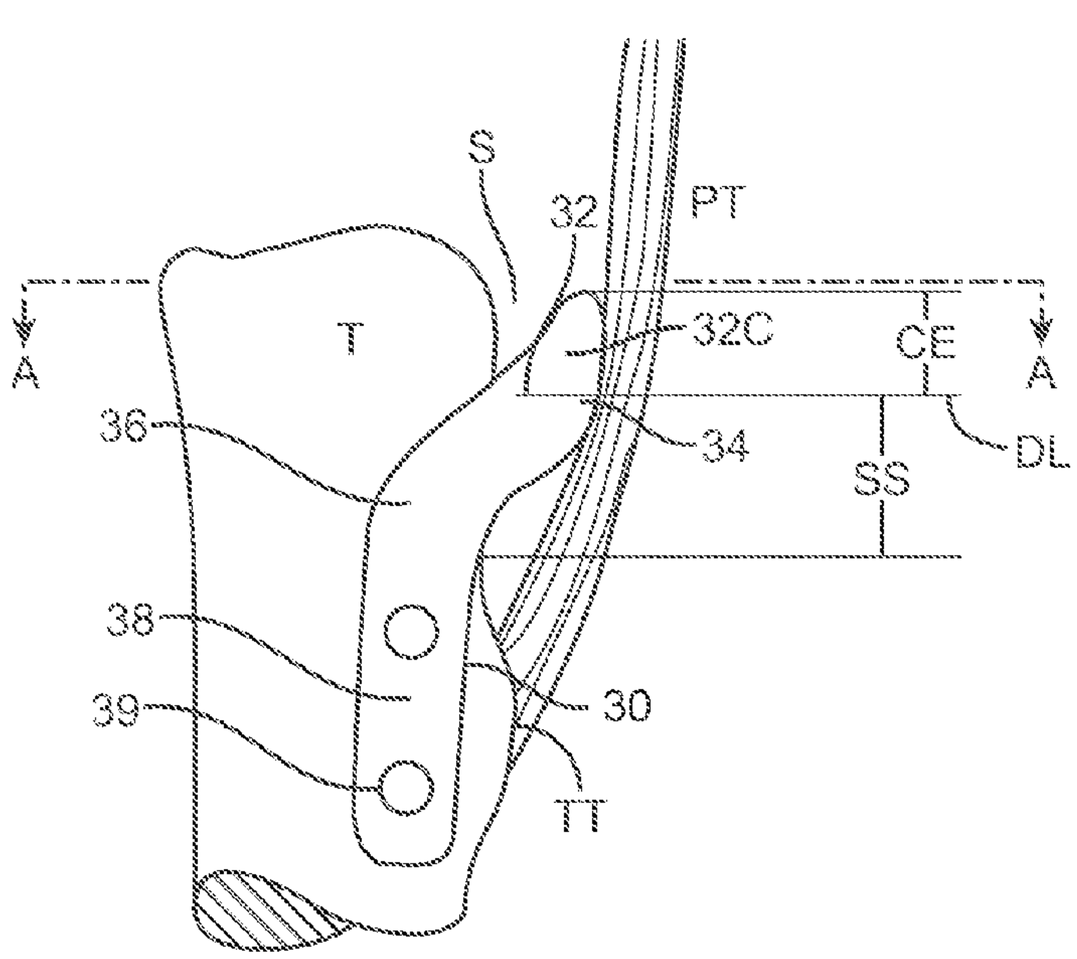
Primary Examiner — Ann Schillinger
(74) *Attorney, Agent, or Firm* — Downs Rachlin Martin PLLC

(57) **ABSTRACT**

Prostheses, methods and related instrumentation for treating disorders of the knee by displacing a connective tissue acting on the patella to alter the location, angle or magnitude of forces exerted by the tissue on the patella so as to achieve a therapeutic effect in patellofemoral compartment of the knee.

26 Claims, 20 Drawing Sheets



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See application file for complete search history.

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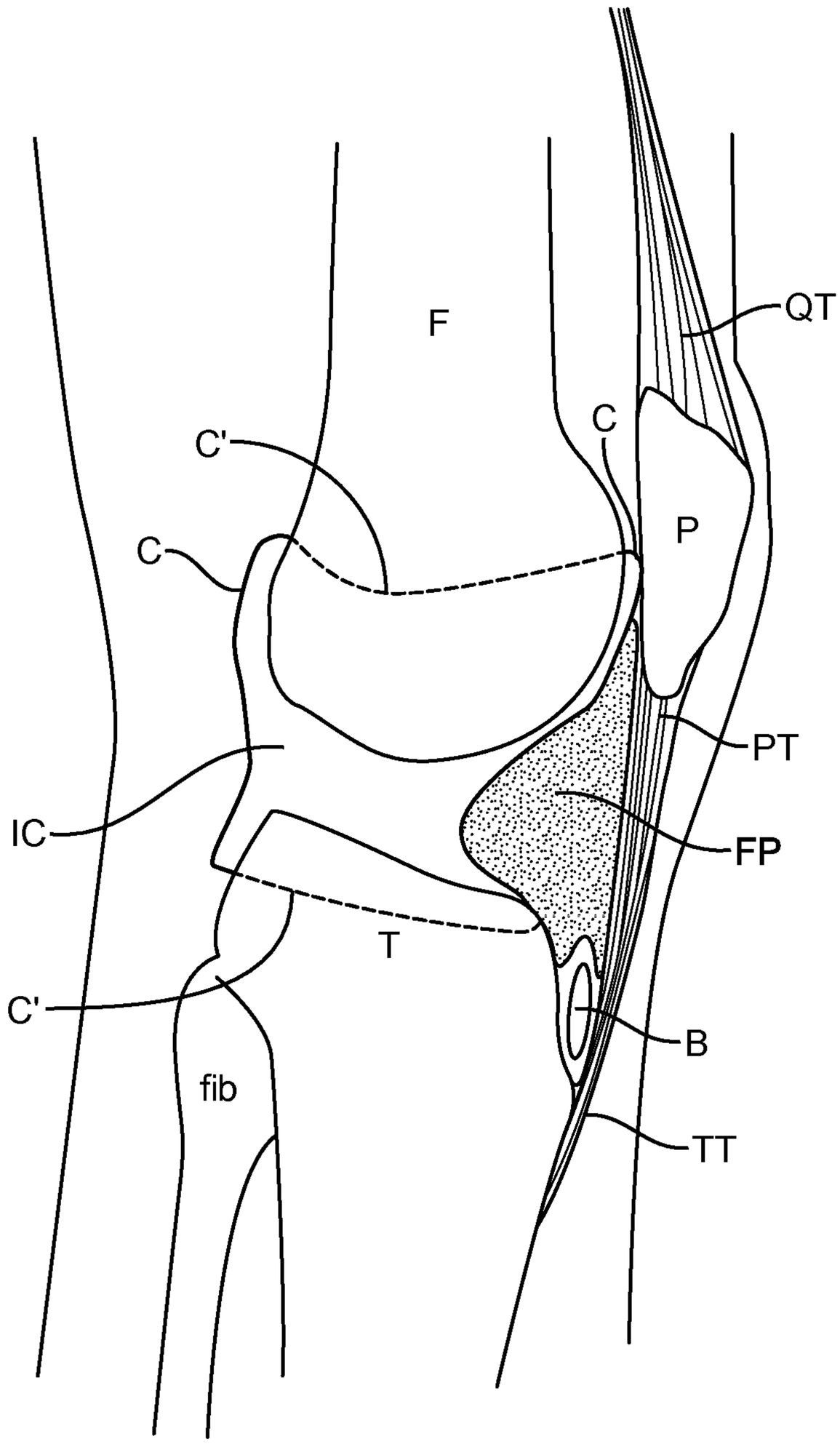

FIG. 1

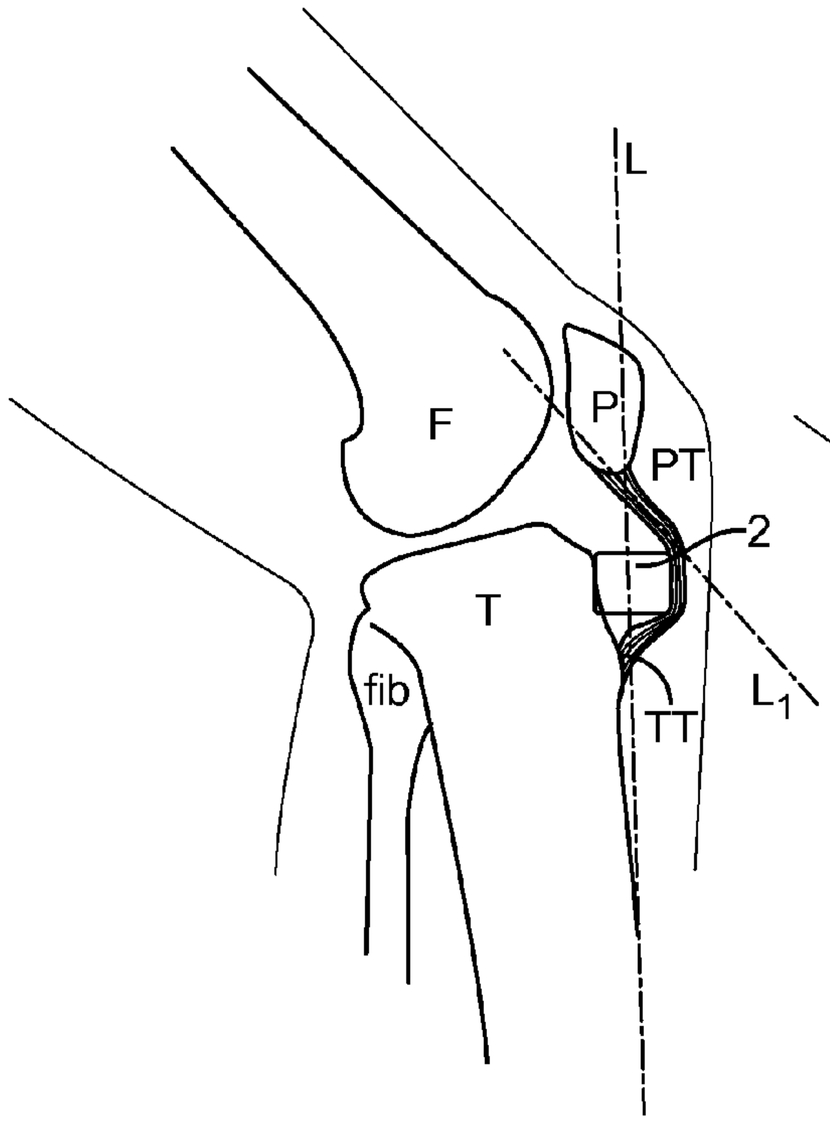

FIG. 2

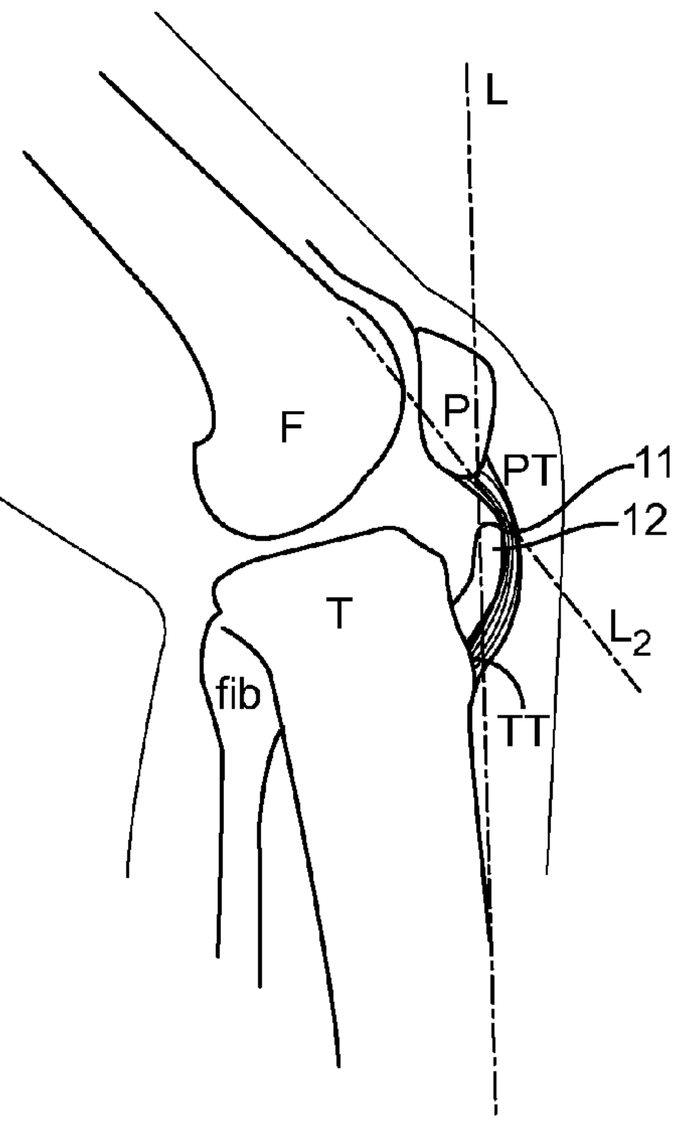

FIG. 3

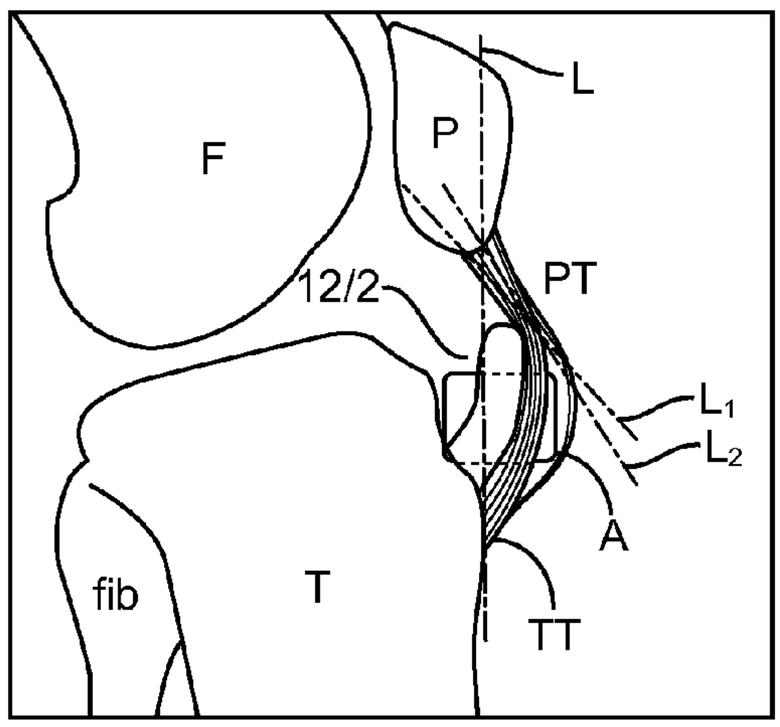

FIG. 3A

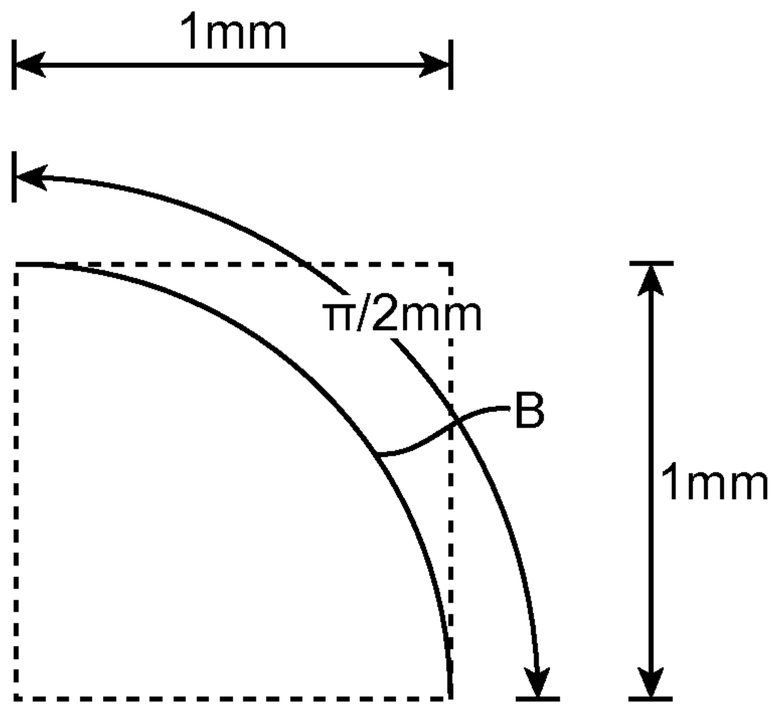

FIG. 4A

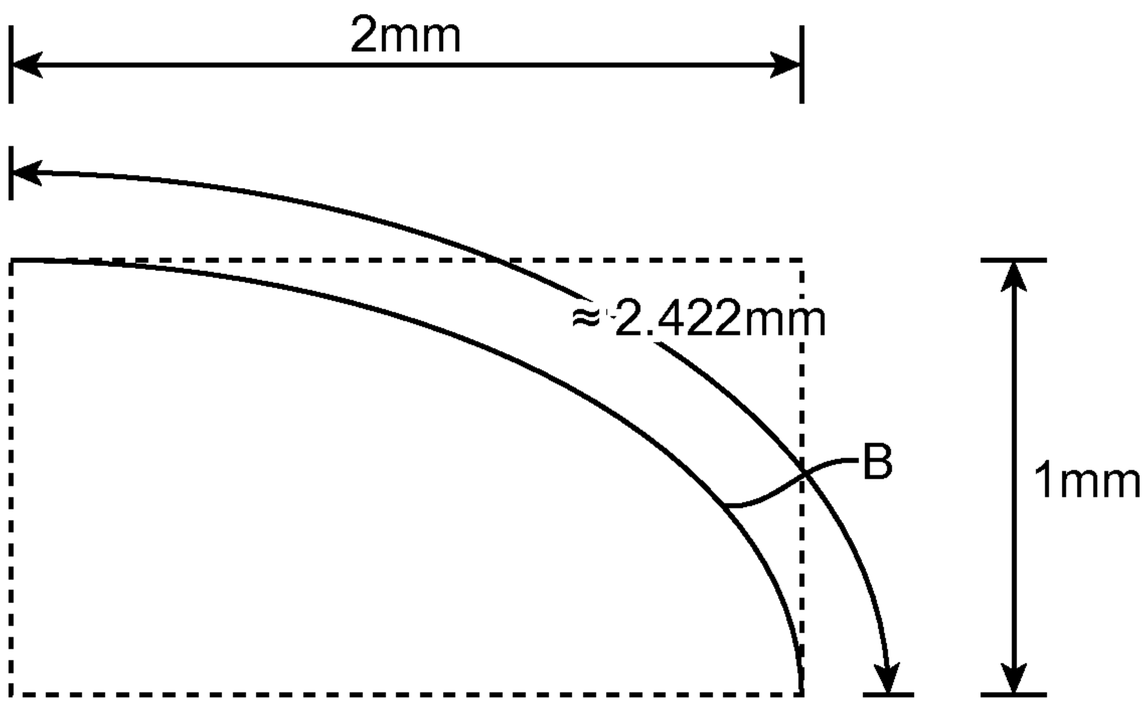

FIG. 4B

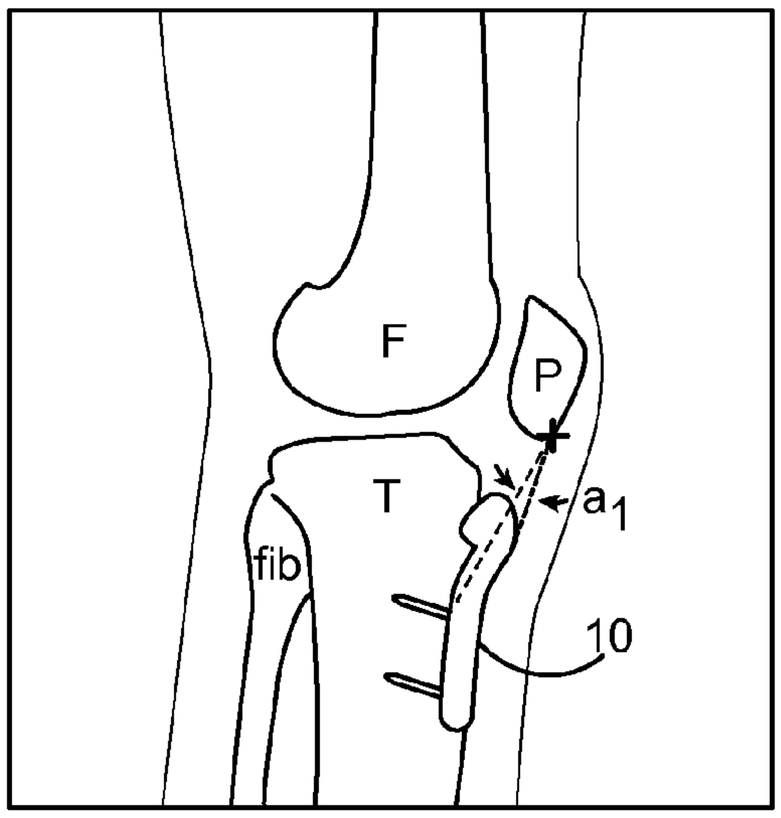

FIG. 5A

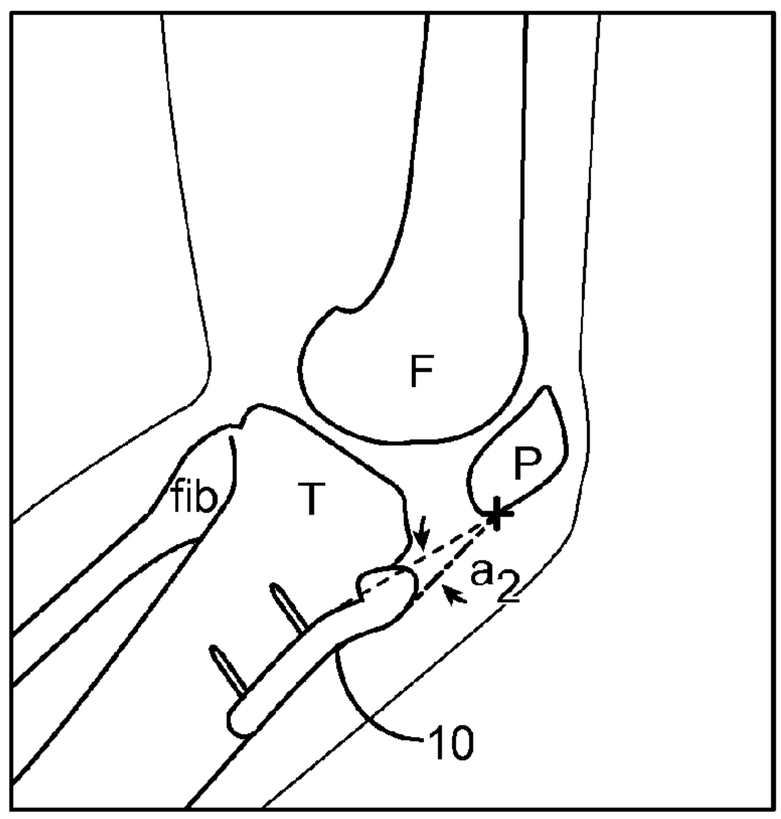

FIG. 5B

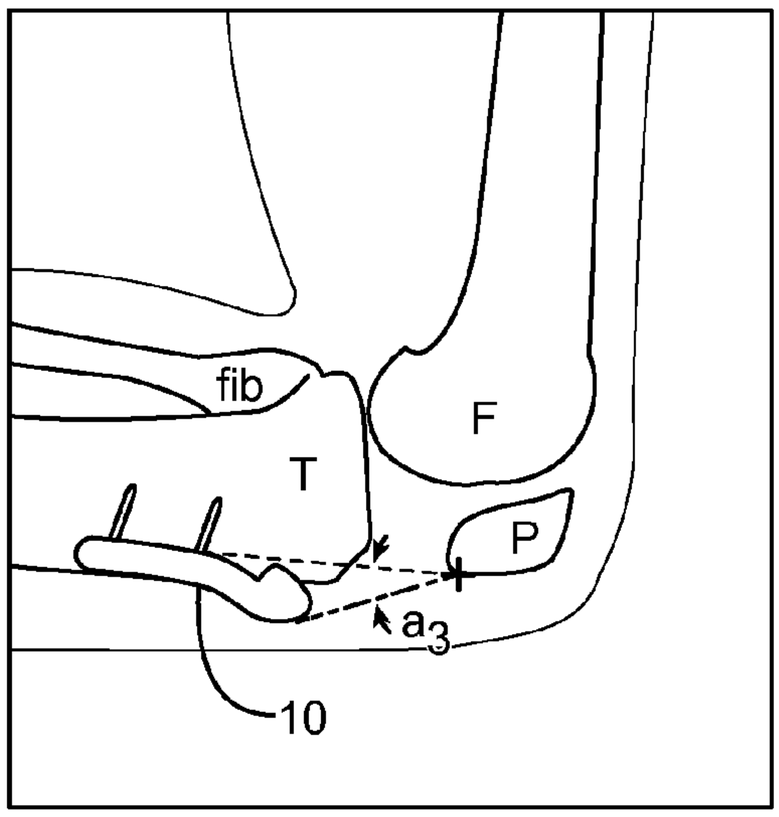

FIG. 5C

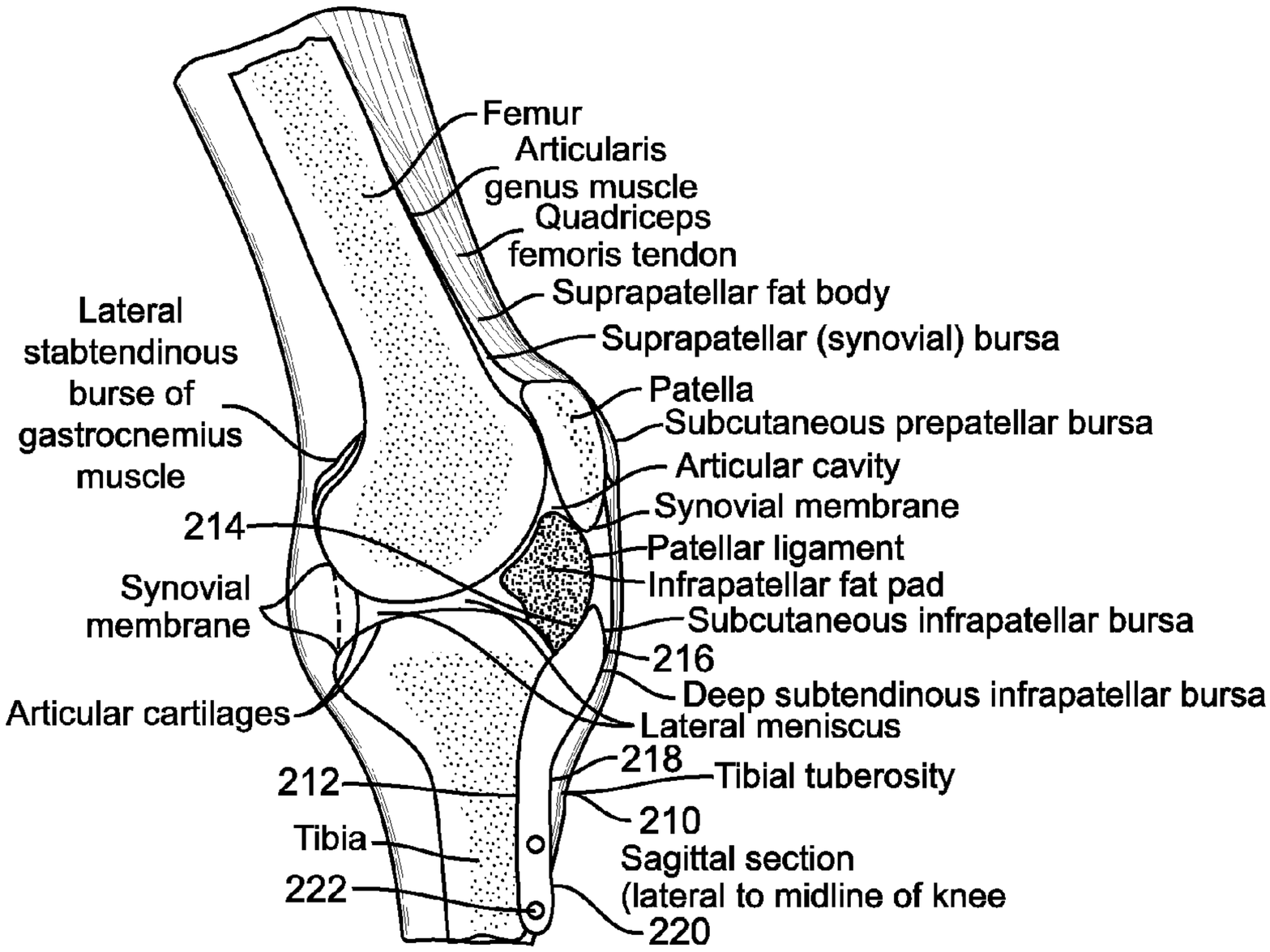
Femur
Articularis
genus muscle
Quadriceps
femoris tendon
Suprapatellar fat body
Suprapatellar (synovial) bursa
Patella
Subcutaneous prepatellar bursa
Articular cavity
Synovial membrane
Patellar ligament
Infrapatellar fat pad
Subcutaneous infrapatellar bursa
216
Deep subtendinous infrapatellar bursa
Lateral meniscus
218
Tibial tuberosity
210
Sagittal section
(lateral to midline of knee
220
Lateral
stabtendinous
burse of
gastrocnemius
muscle
214
Synovial
membrane
Articular cartilages
212
Tibia
222

FIG. 6A

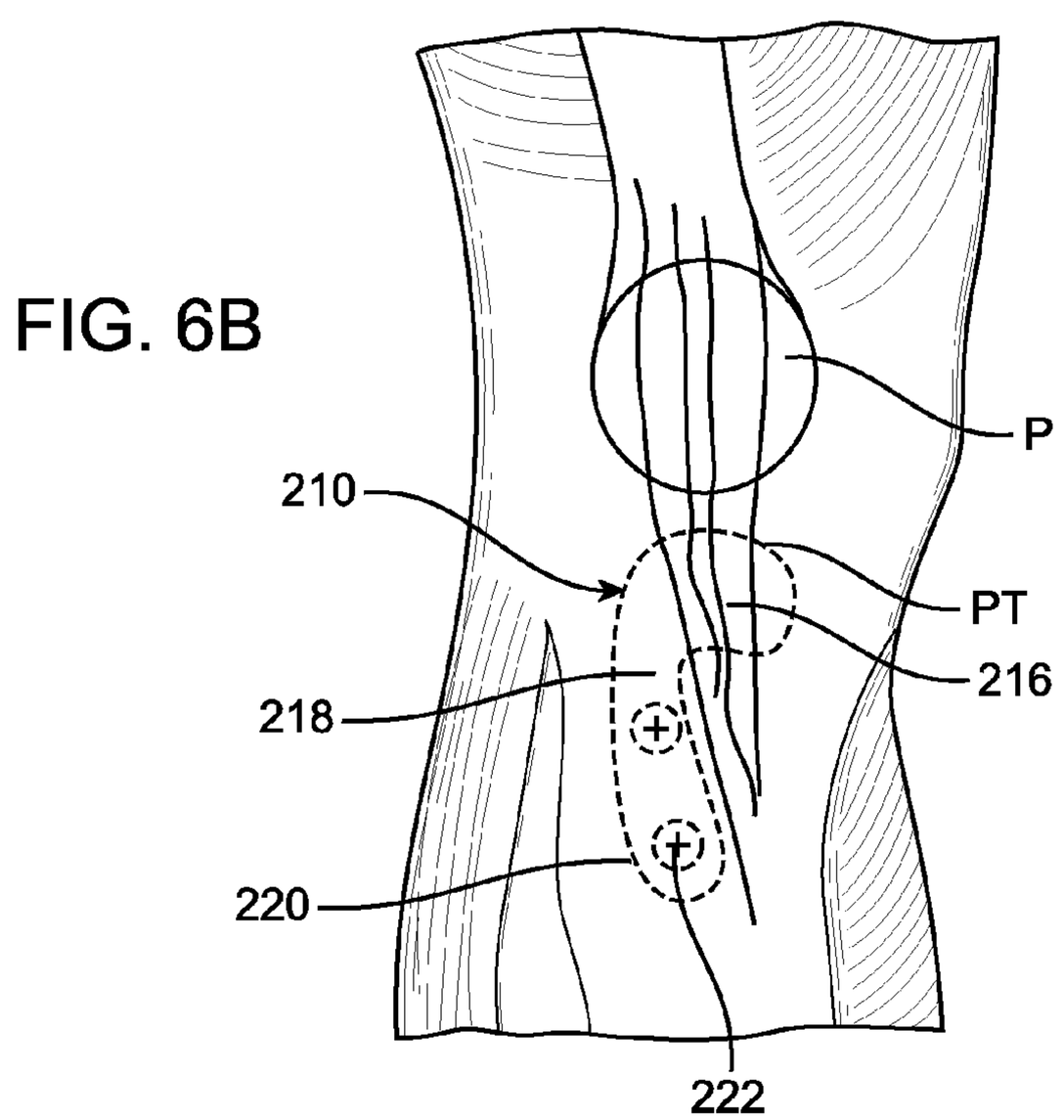
P
210
PT
216
218
220
222

FIG. 6B

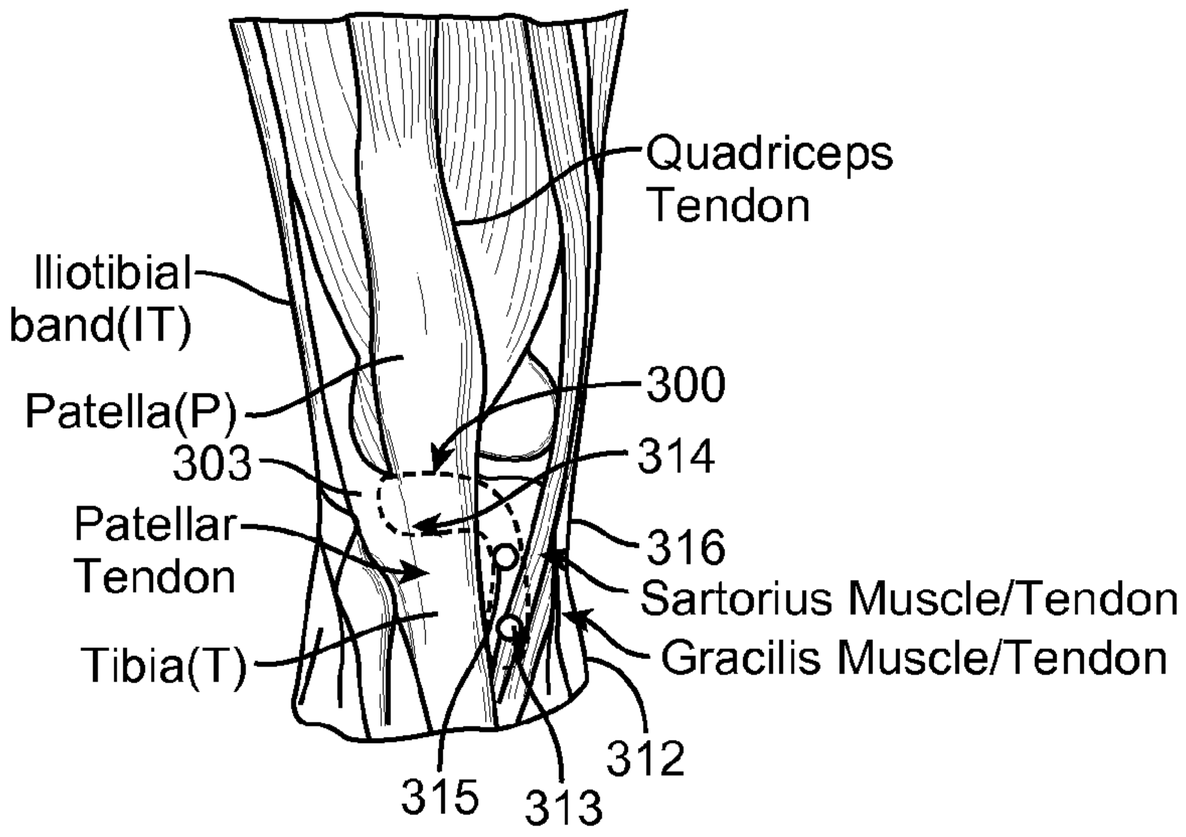
Quadriceps
Tendon
Iliotibial
band(IT)
Patella(P)
303
Patellar
Tendon
Tibia(T)
300
314
316
Sartorius Muscle/Tendon
Gracilis Muscle/Tendon
312
315
313

FIG. 7A

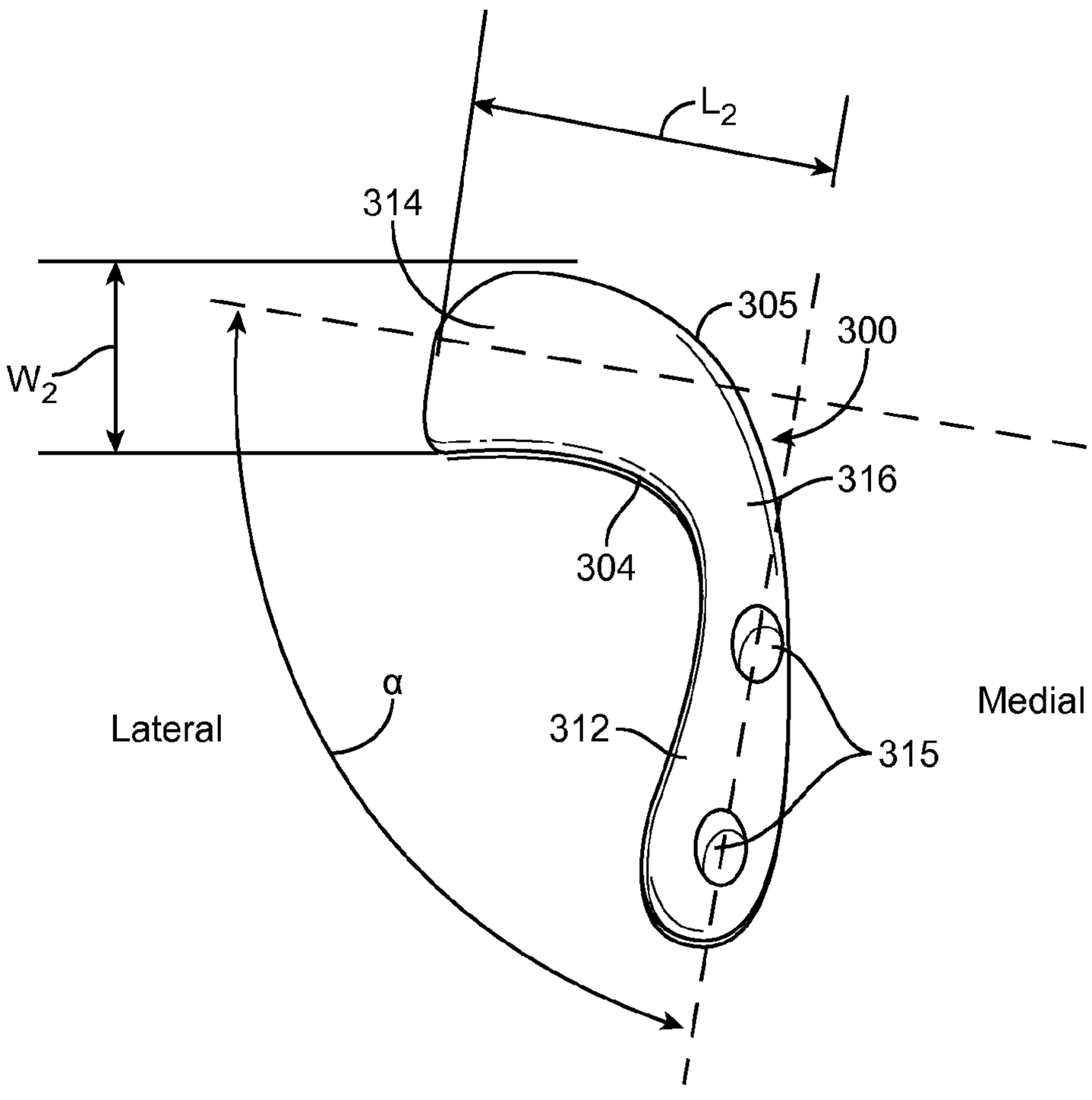
L_2
314
305
300
W_2
316
304
α
Lateral
312
Medial
315

FIG. 7B

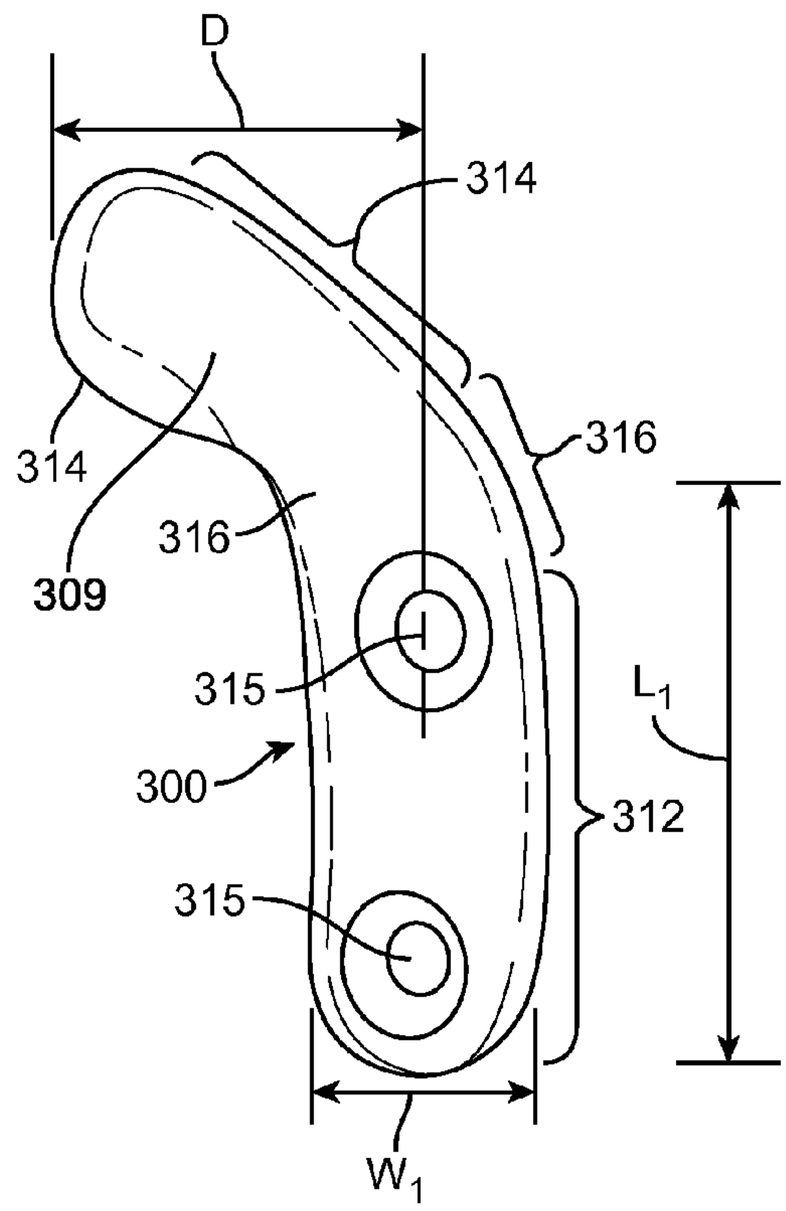

FIG. 7C

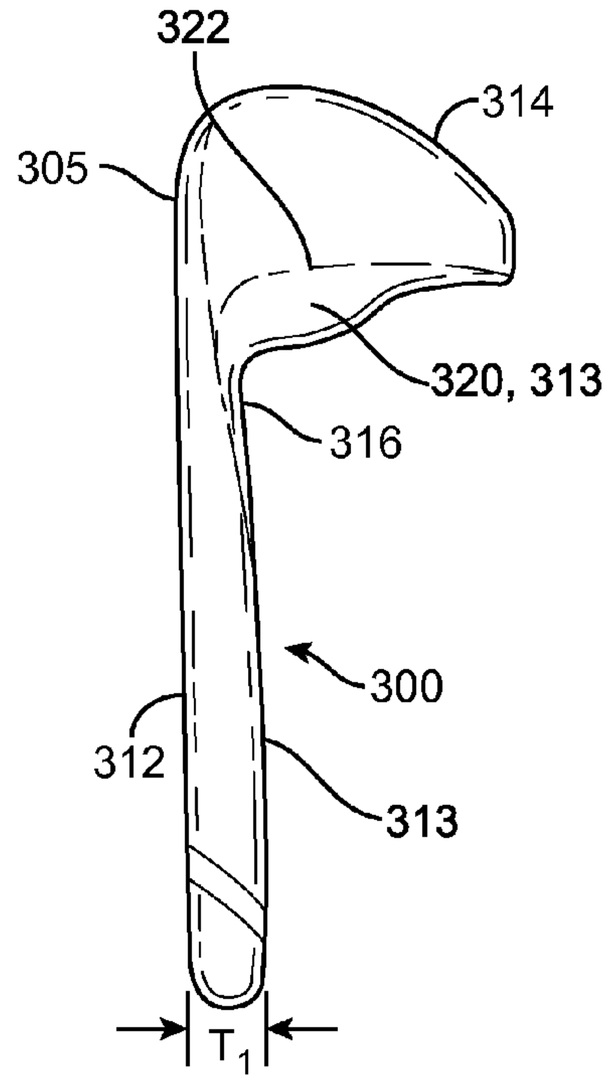

FIG. 7D

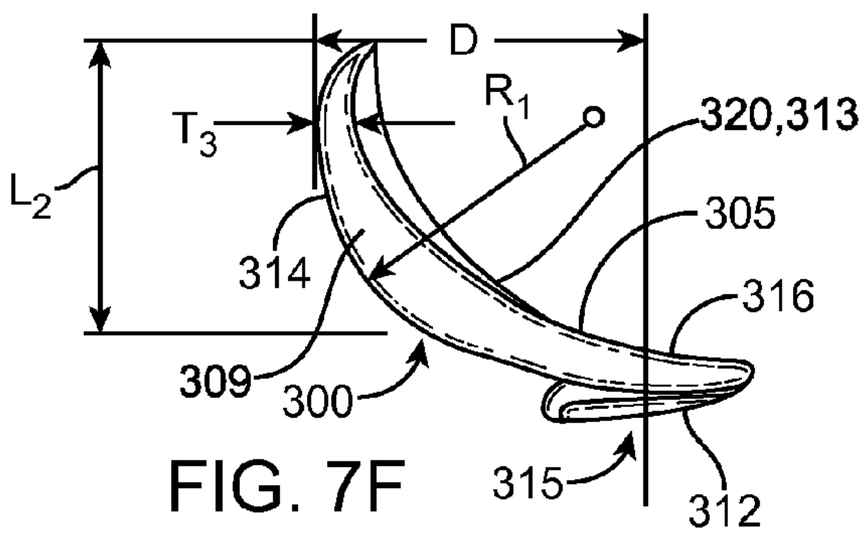

FIG. 7F

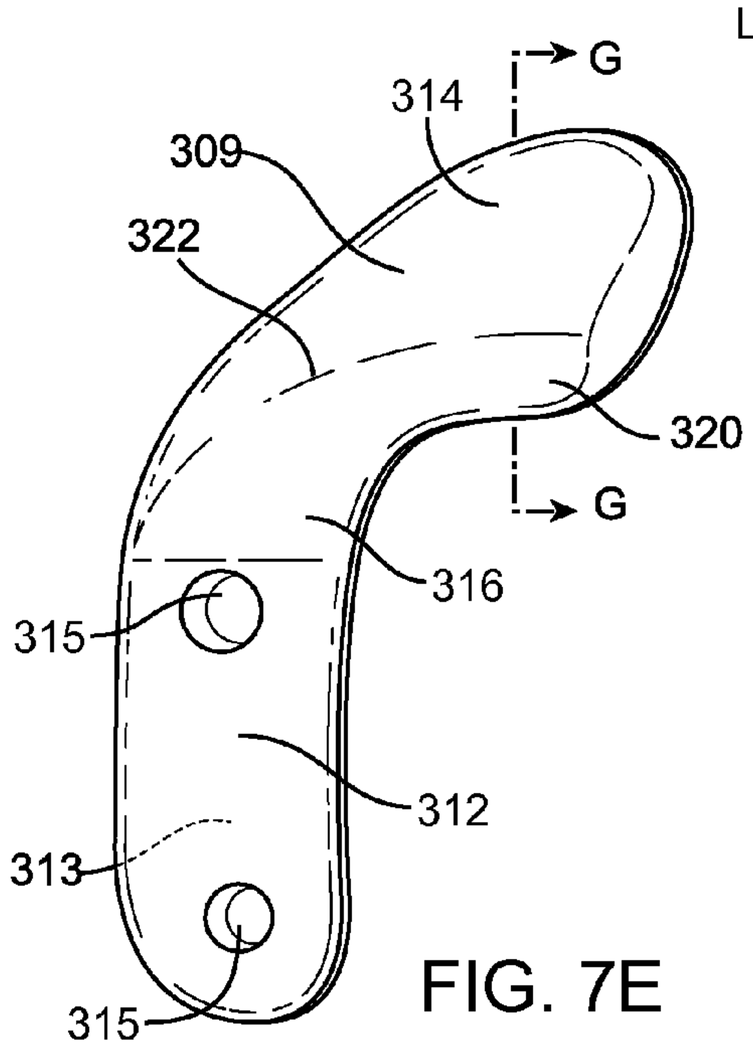

FIG. 7E

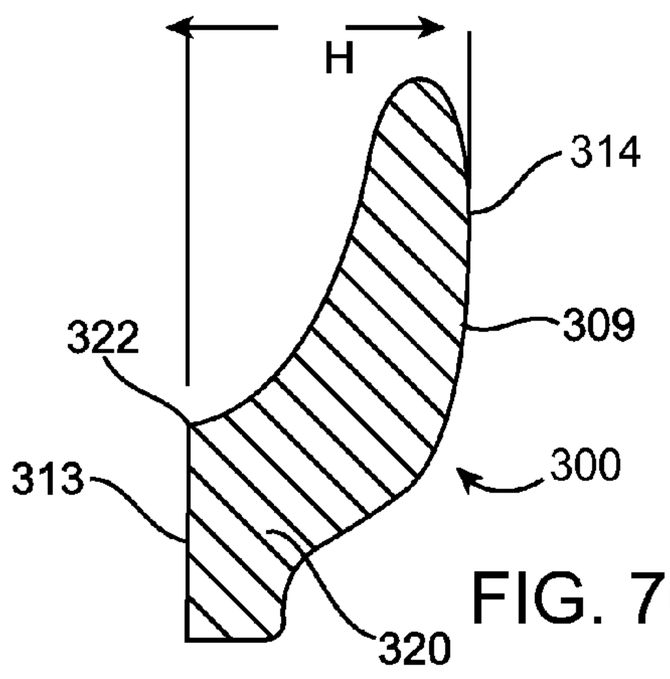

FIG. 7G

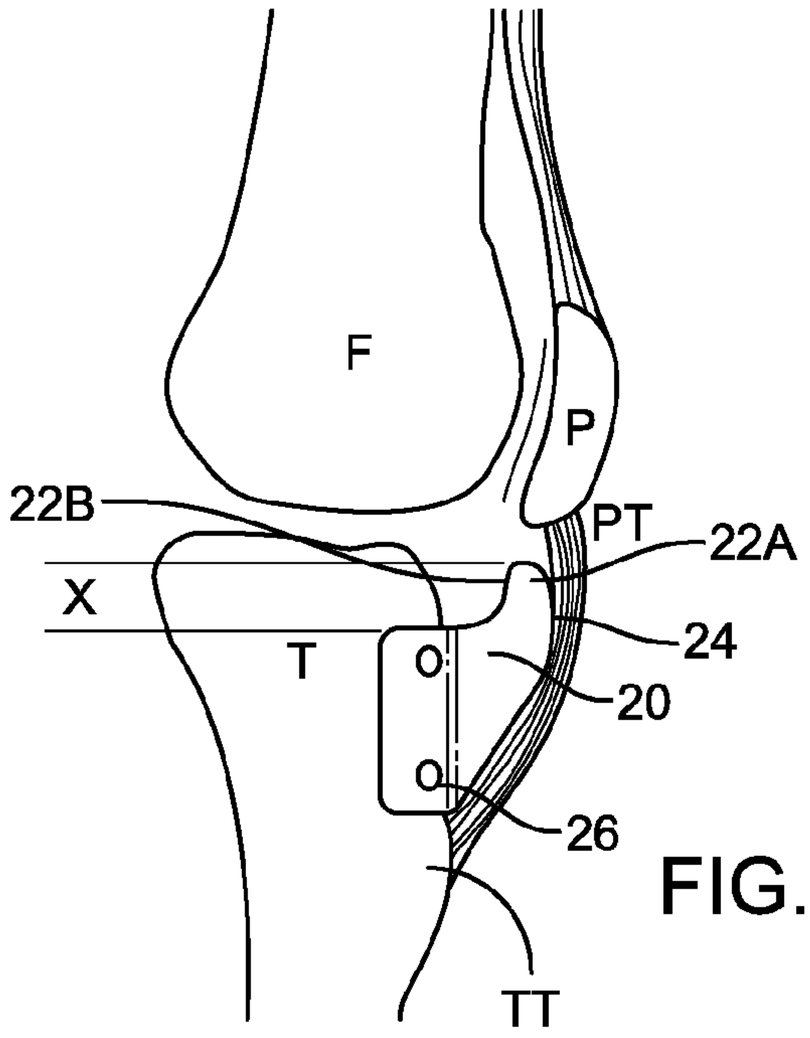

FIG. 8A

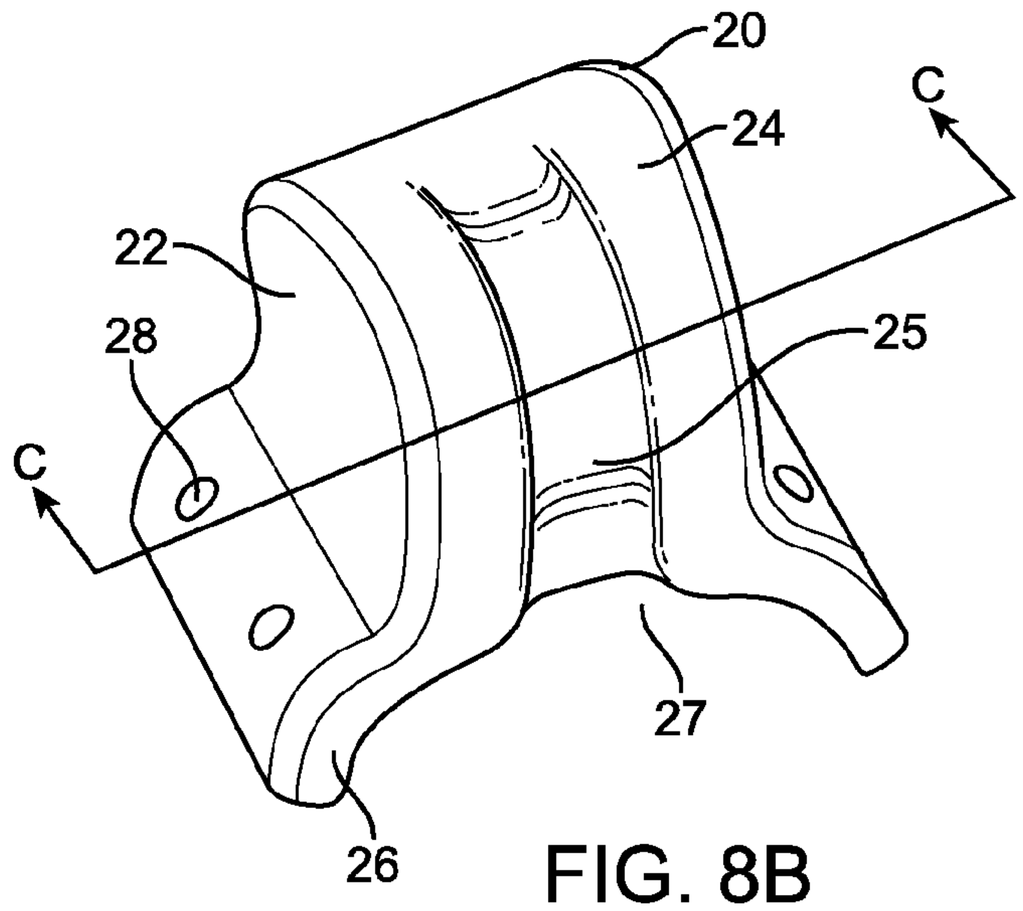

FIG. 8B

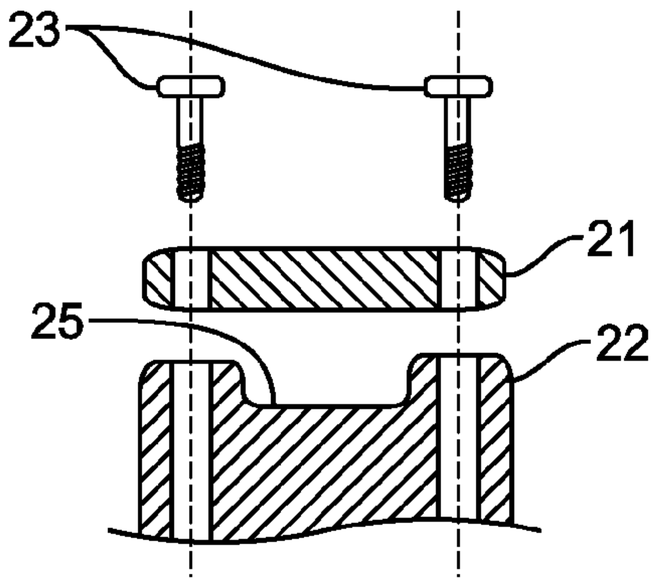

FIG. 8C

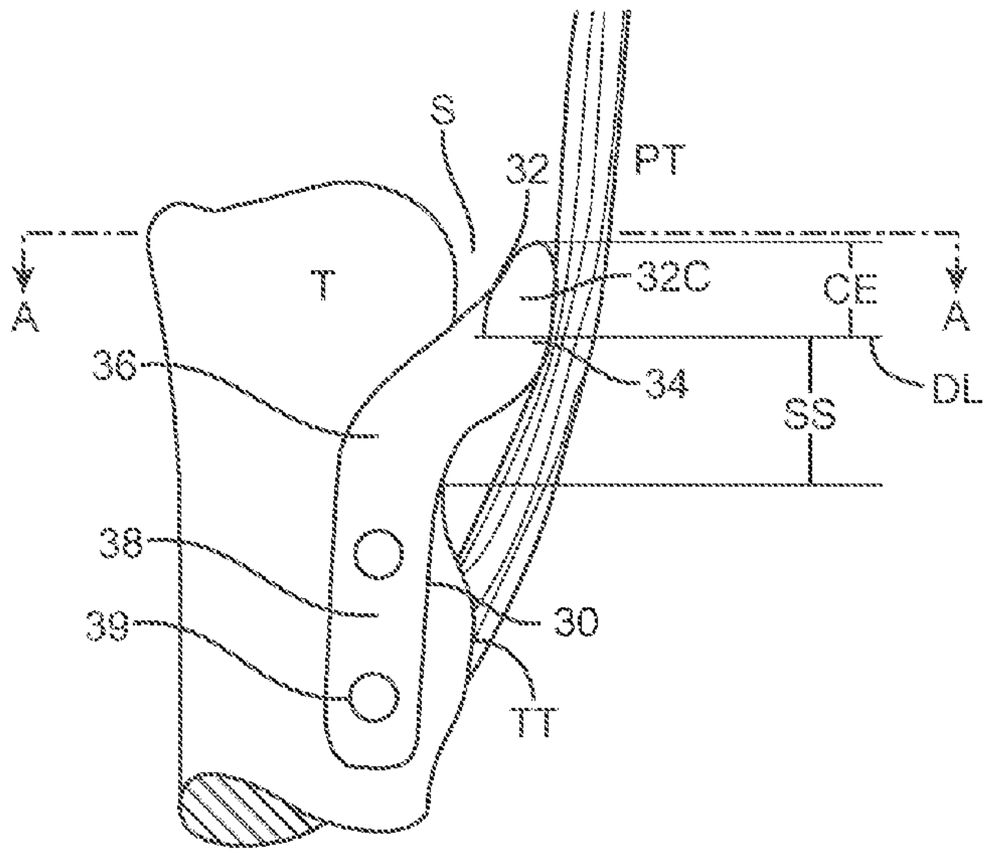

FIG. 9A

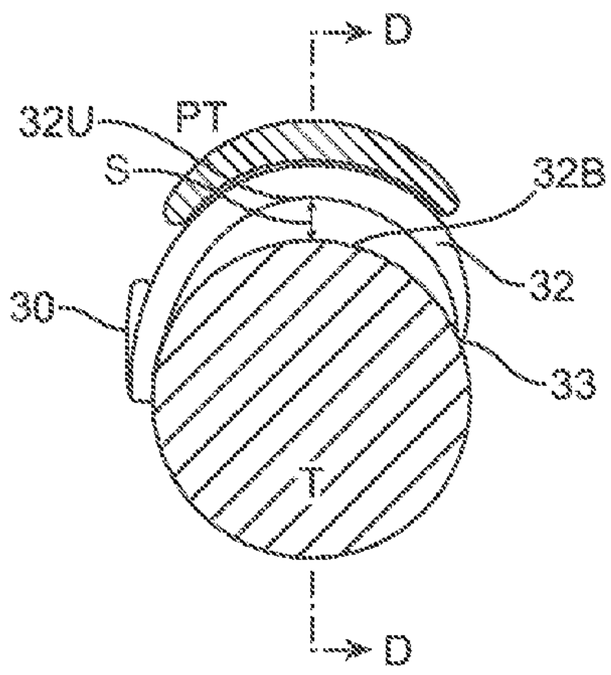

FIG. 9B

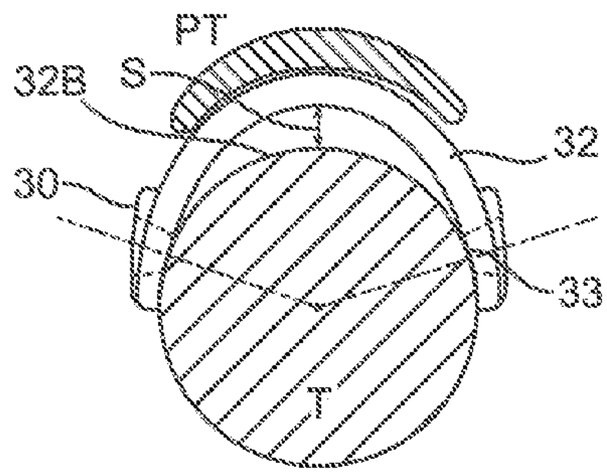

FIG. 9C

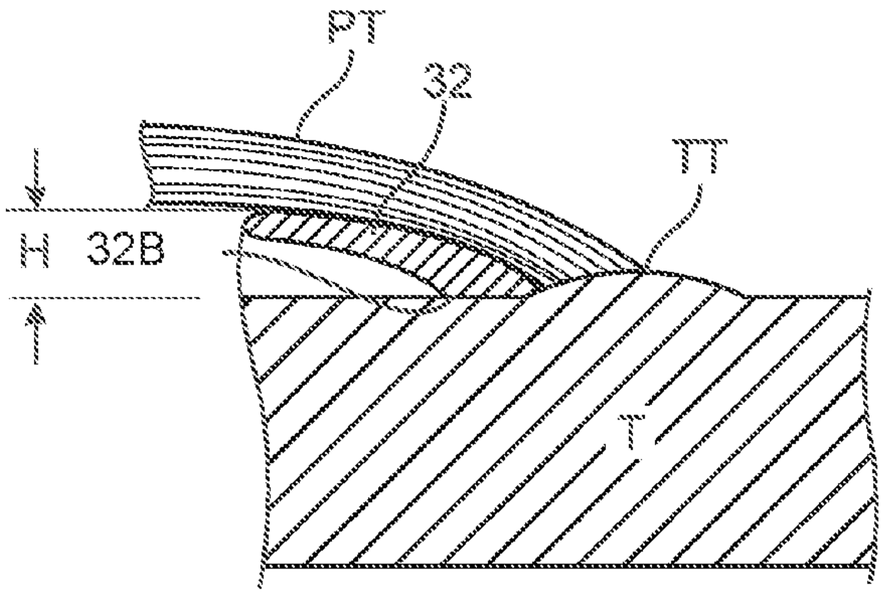

FIG. 9D

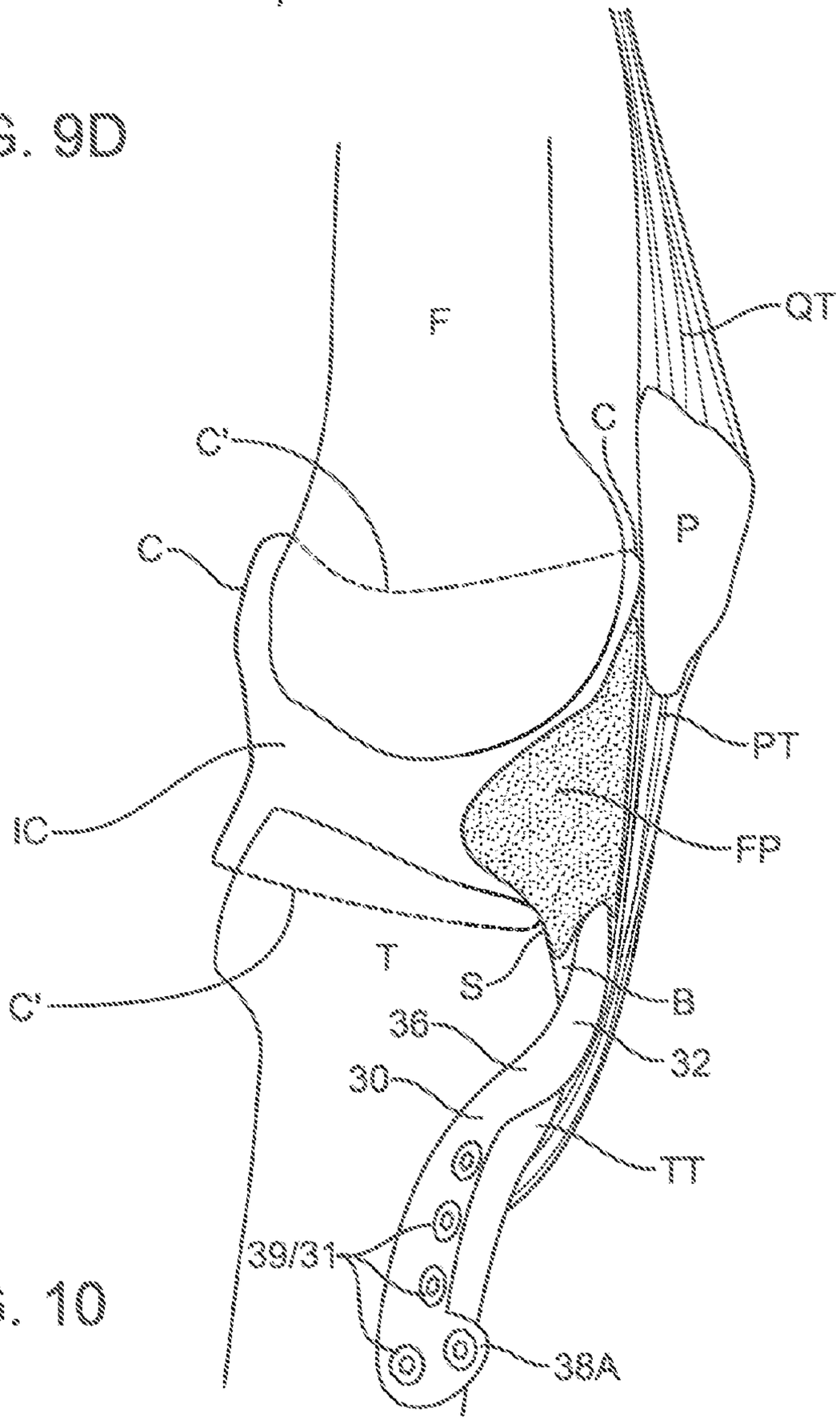

FIG. 10

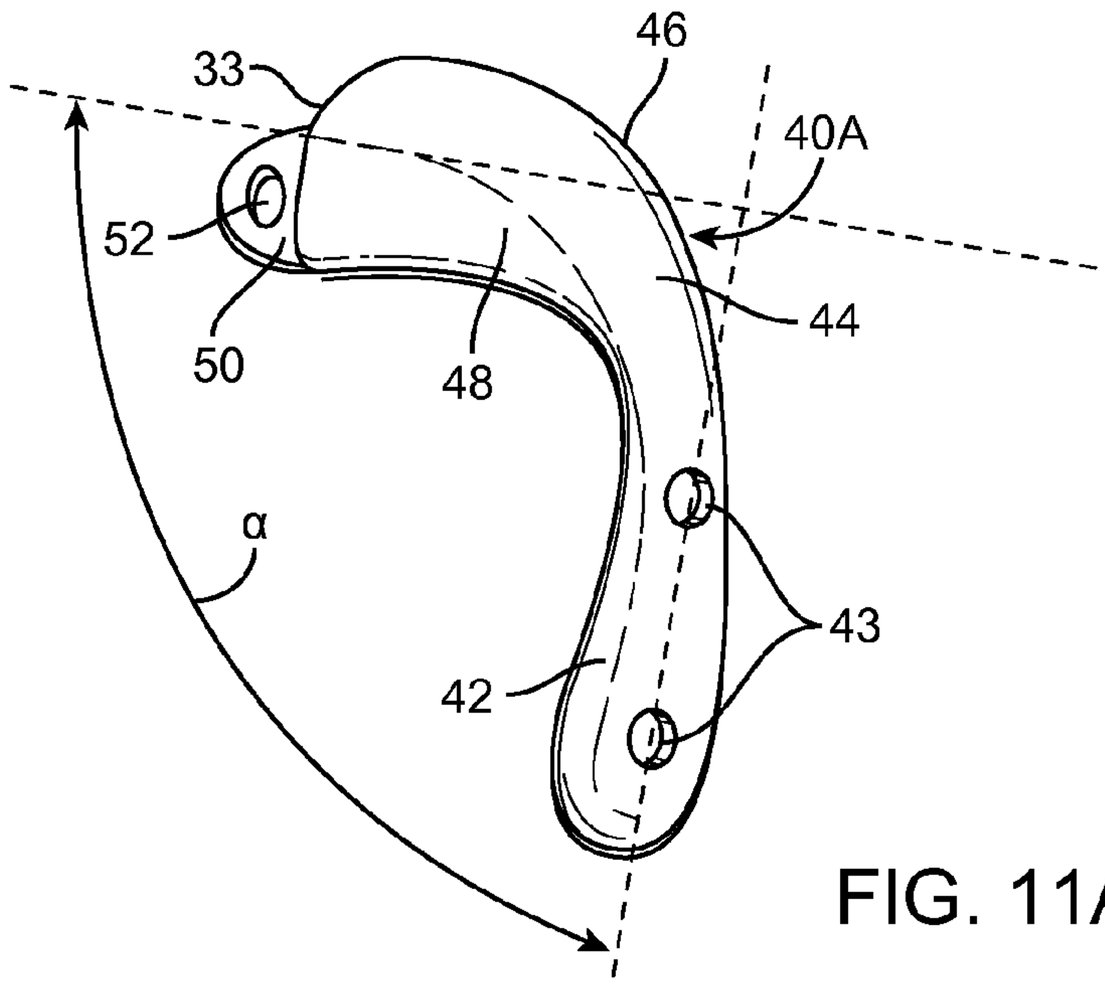

FIG. 11A

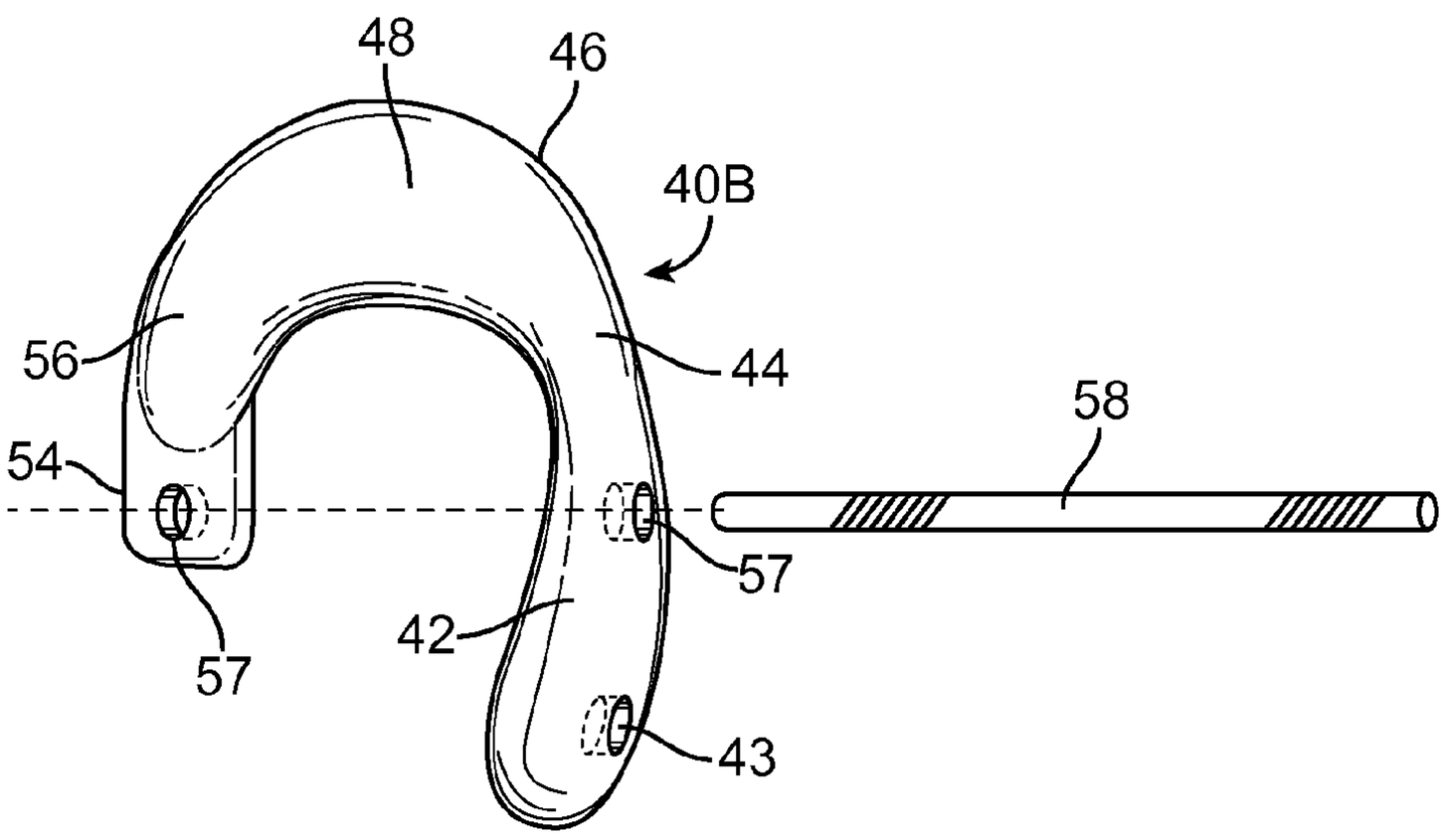

FIG. 11B

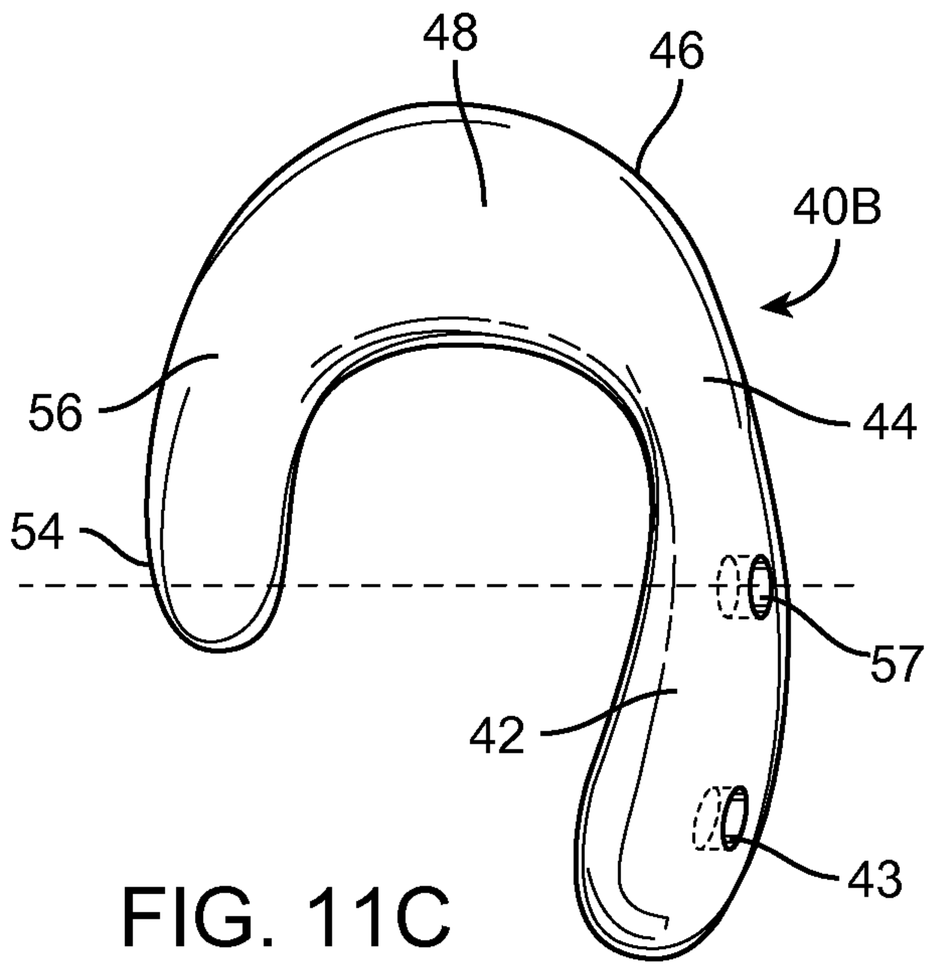

FIG. 11C

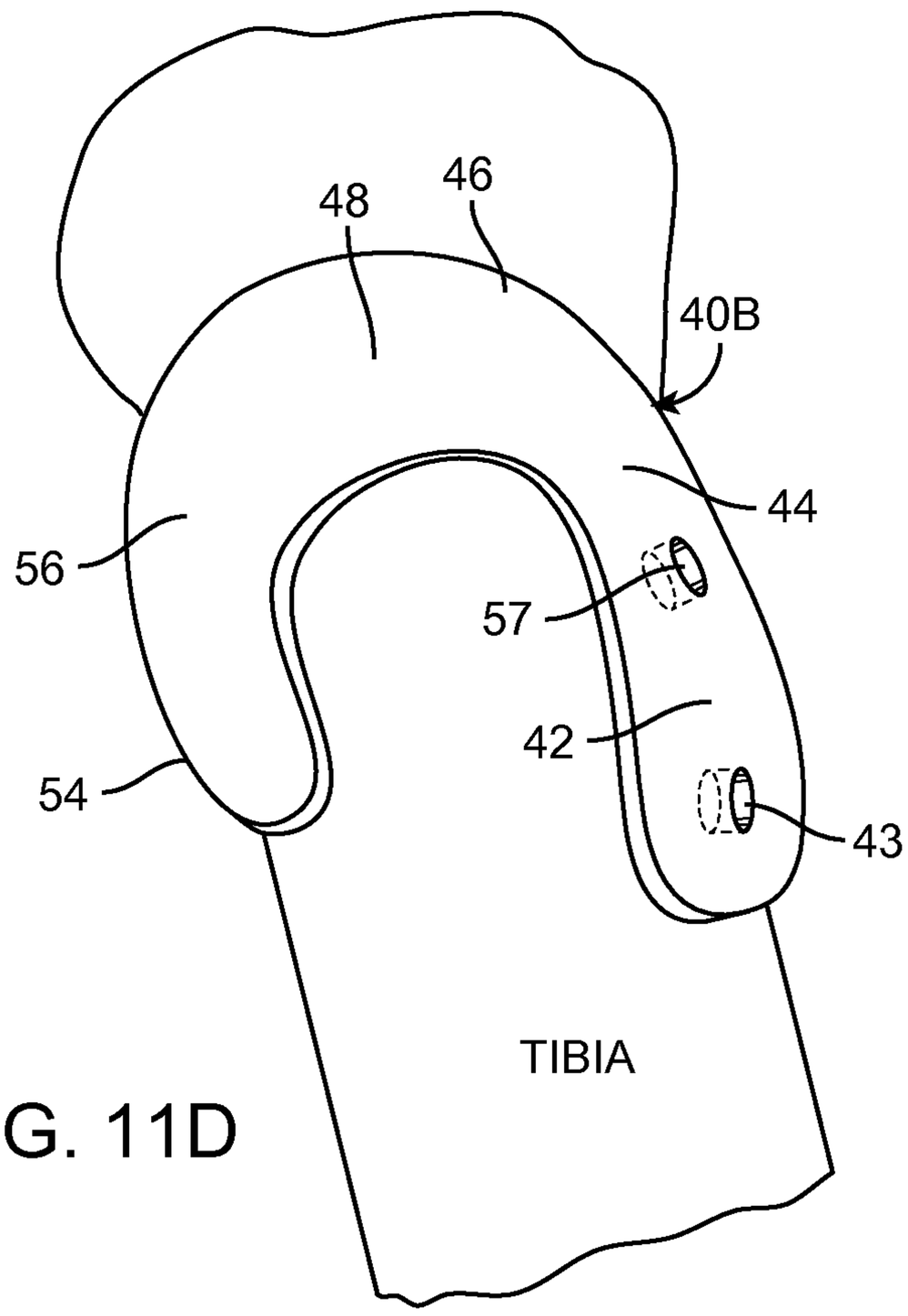

FIG. 11D

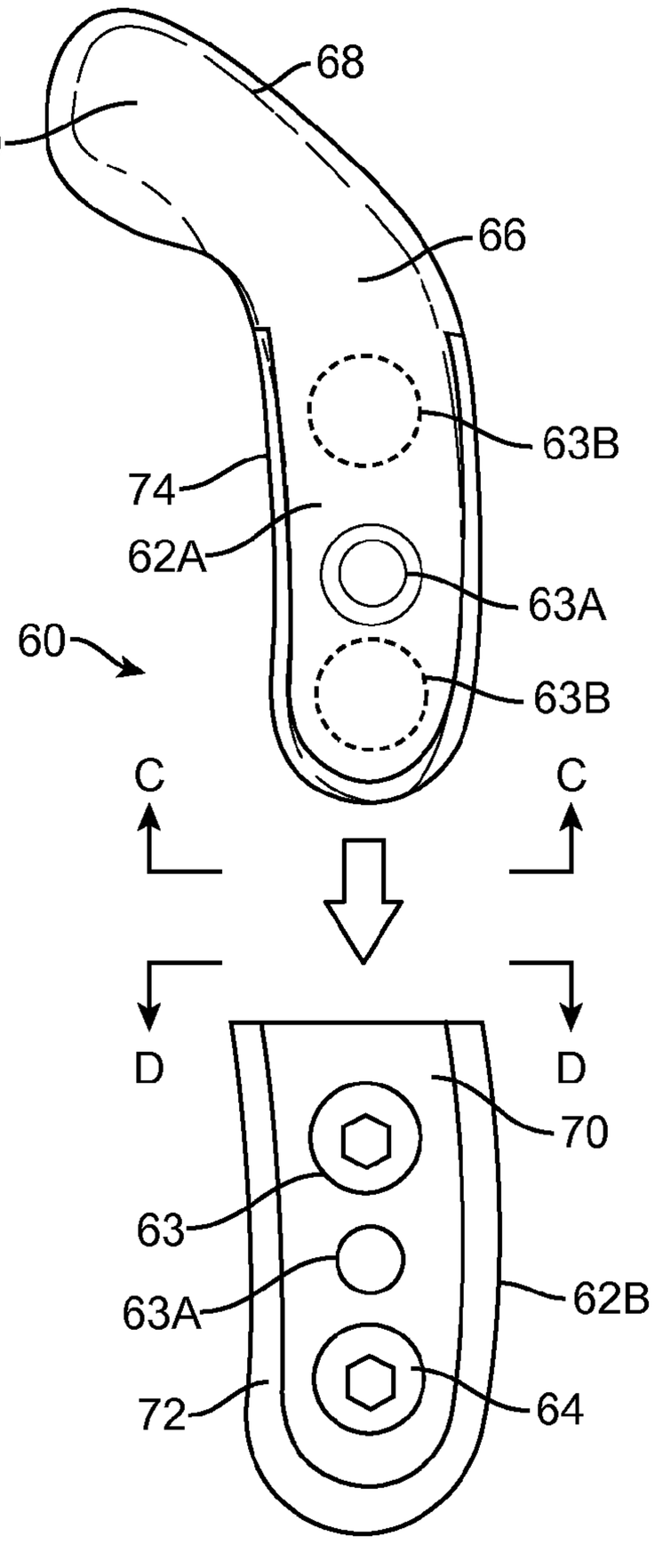

FIG. 12A

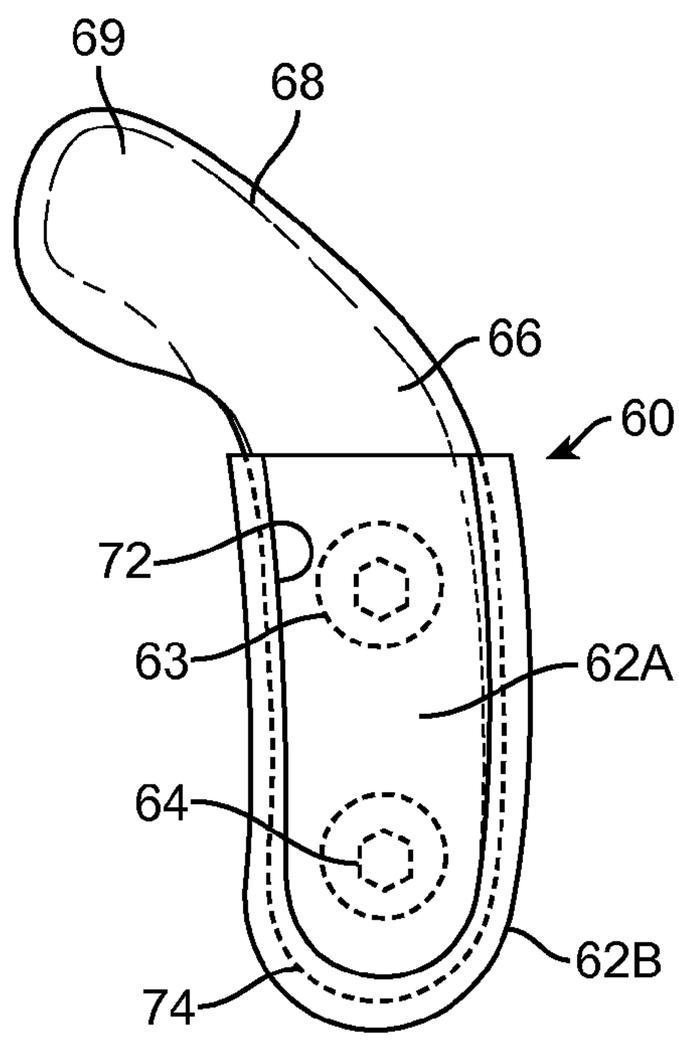

FIG. 12B

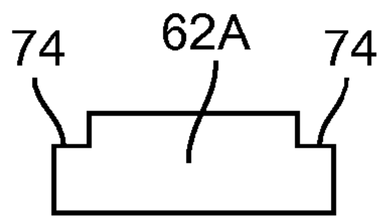

FIG. 12C

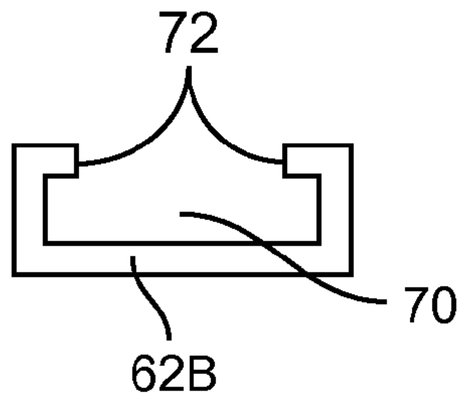

FIG. 12D

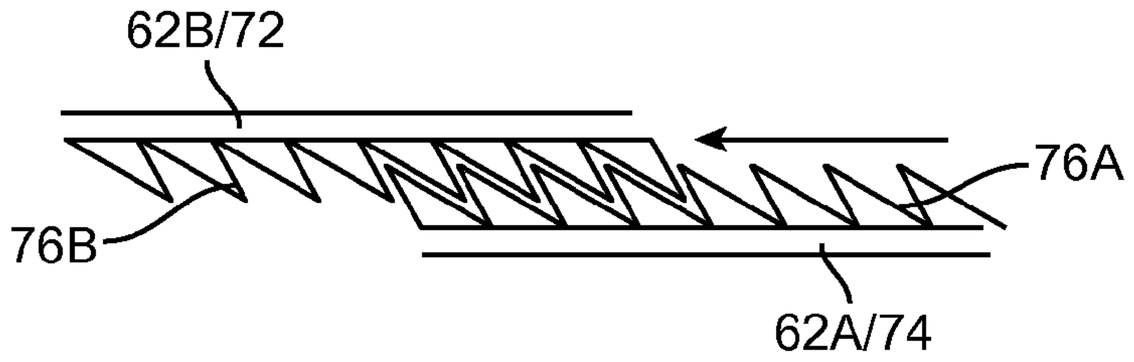

FIG. 12E

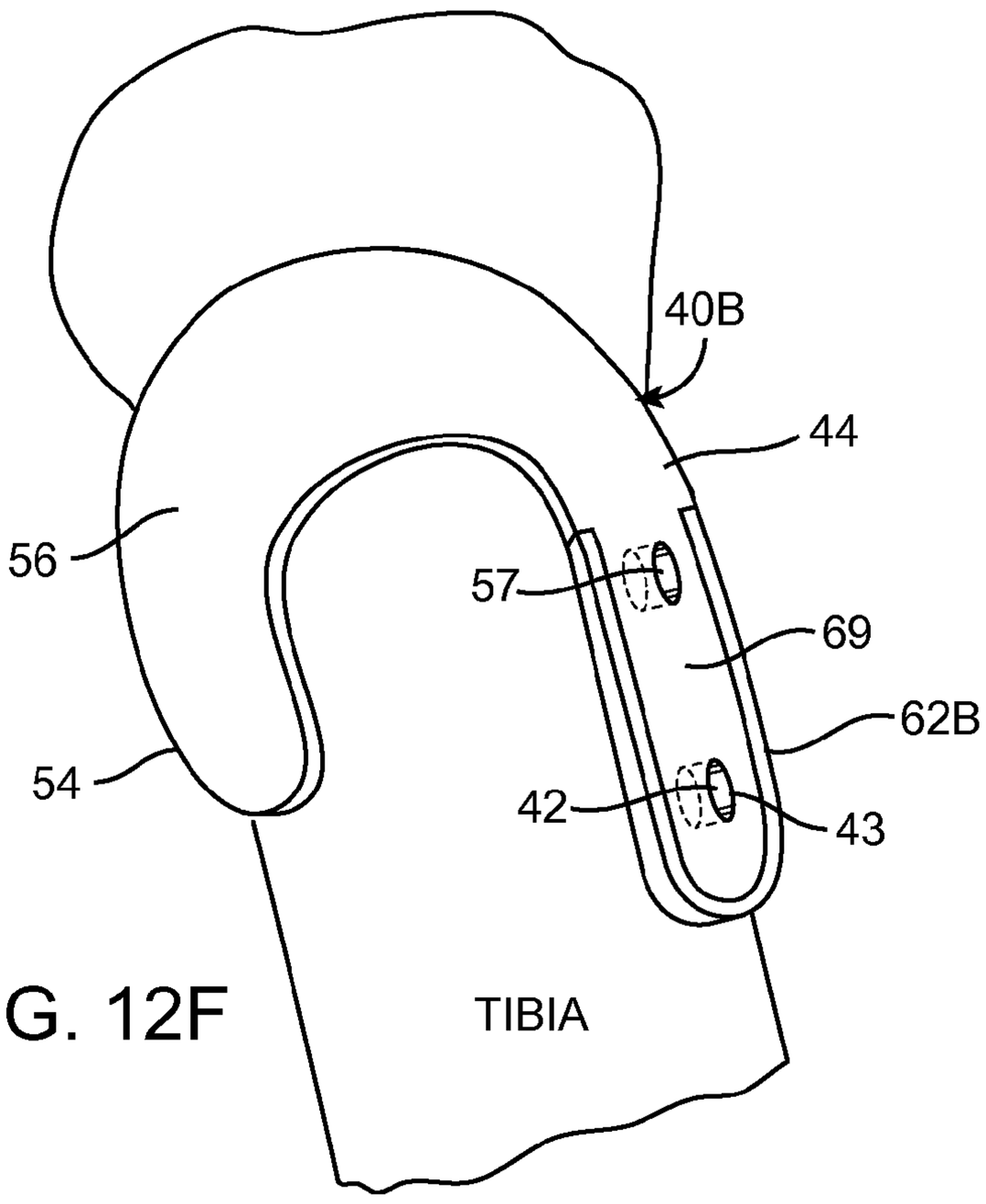

FIG. 12F

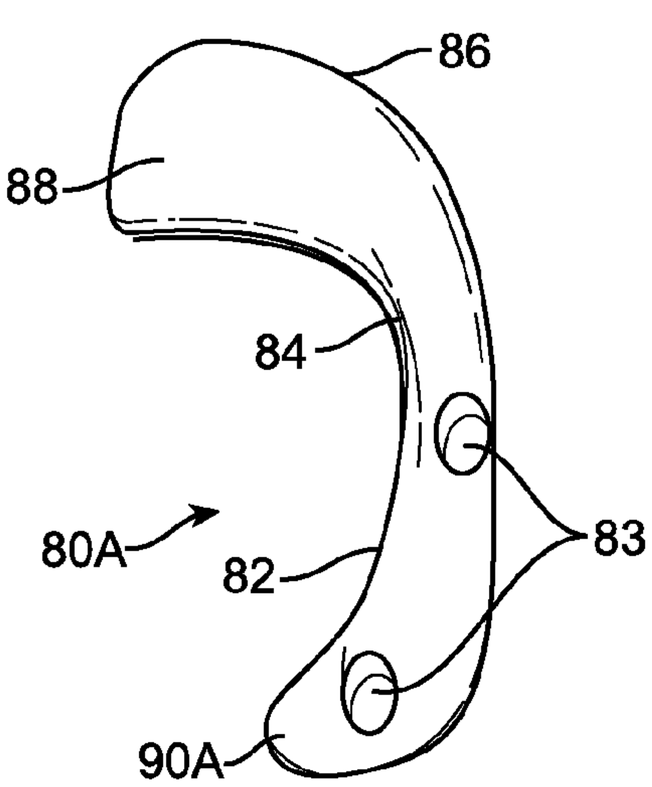

FIG. 13A

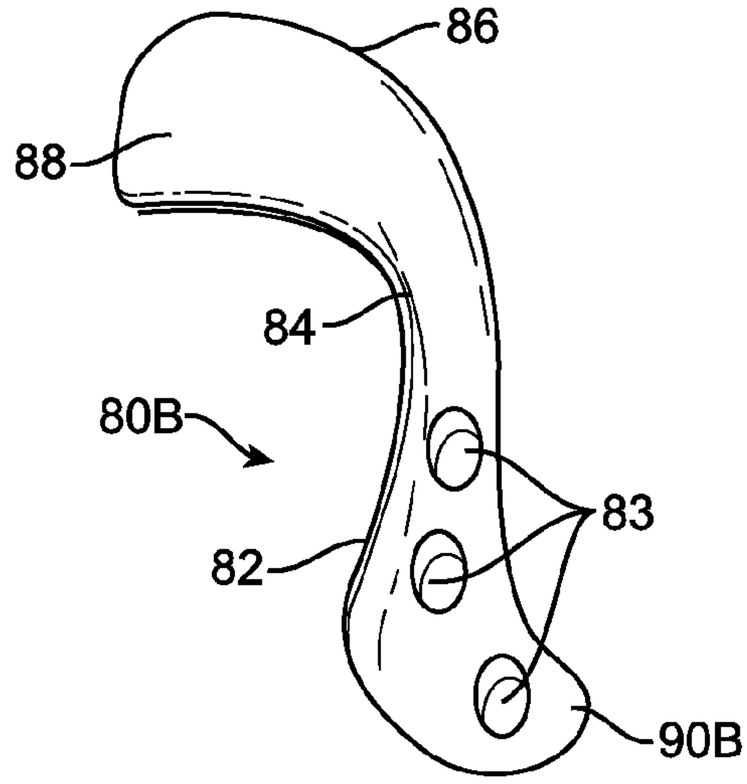

FIG. 13B

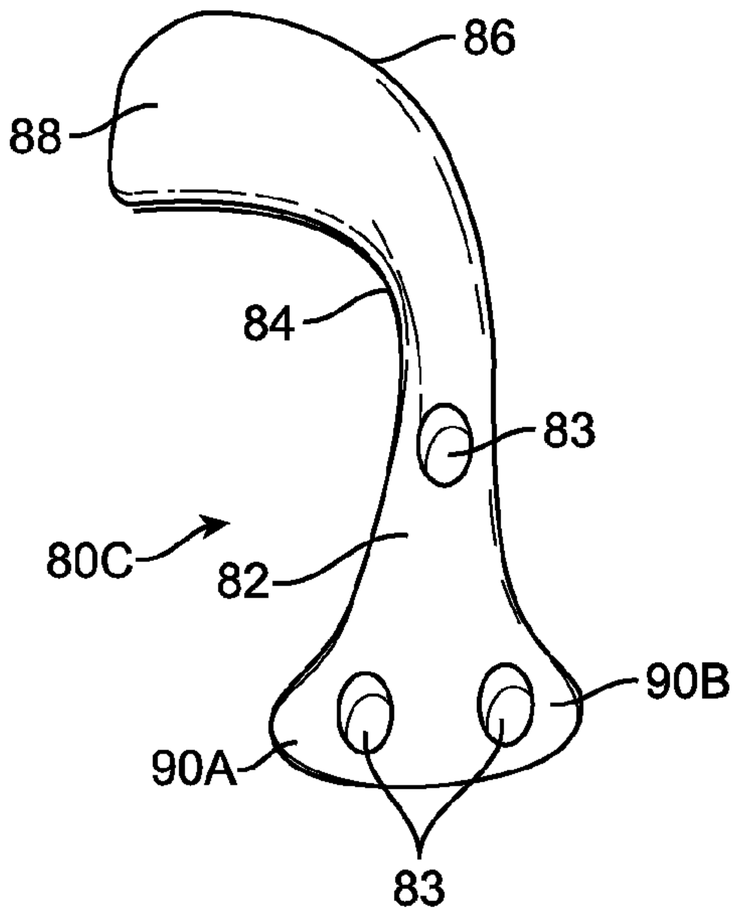

FIG. 13C

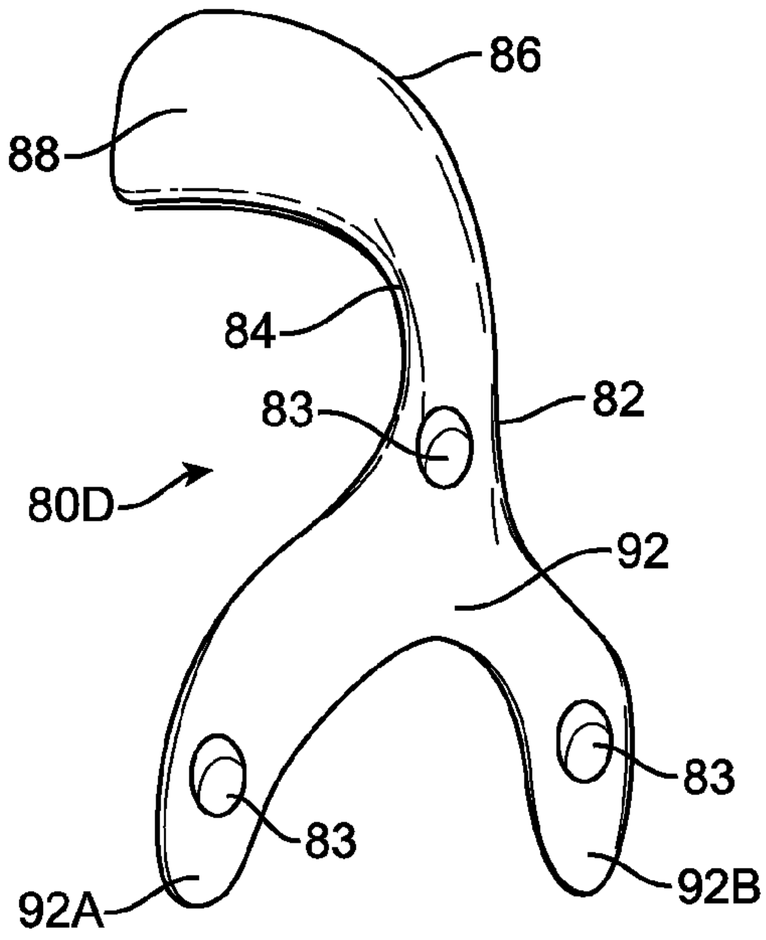

FIG. 13D

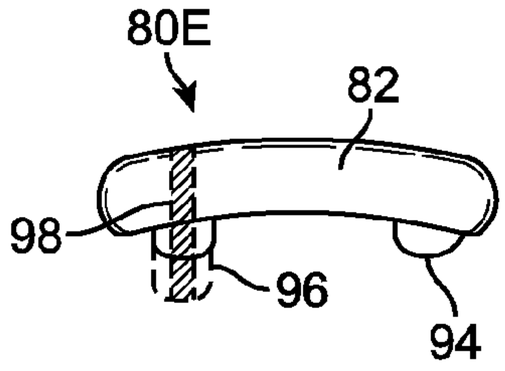

FIG. 13E

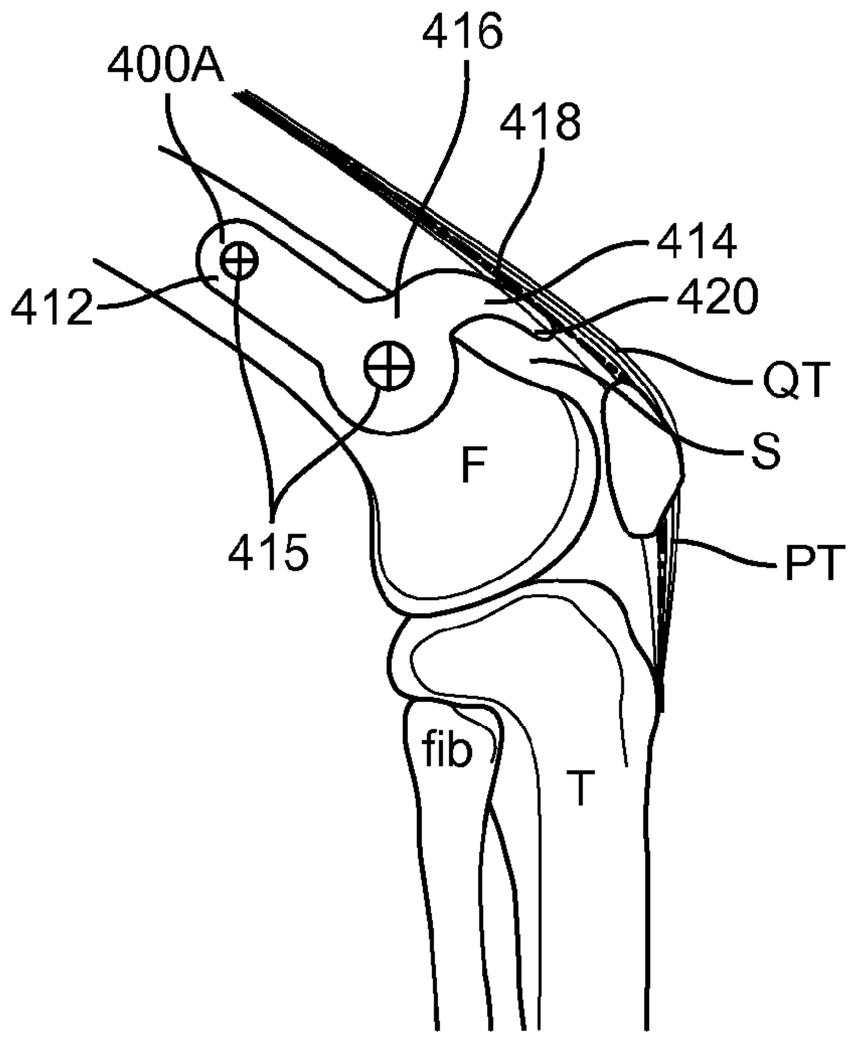

FIG. 14A

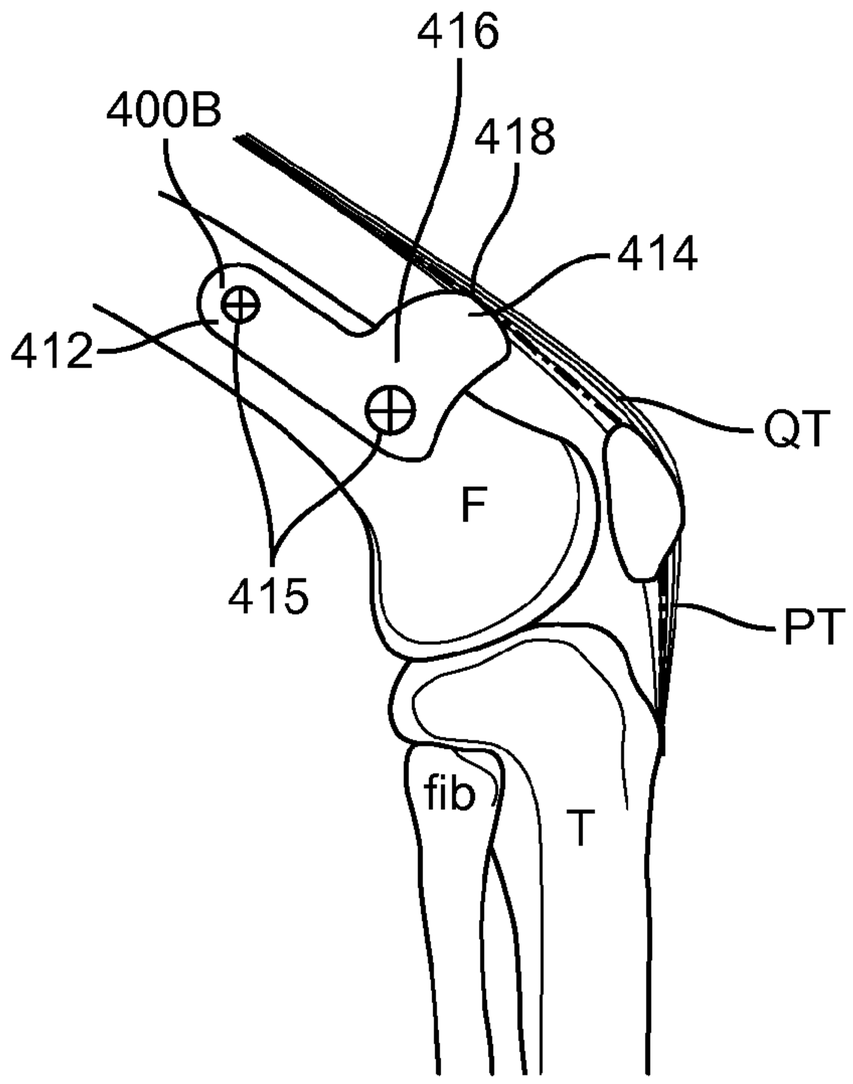

FIG. 14B

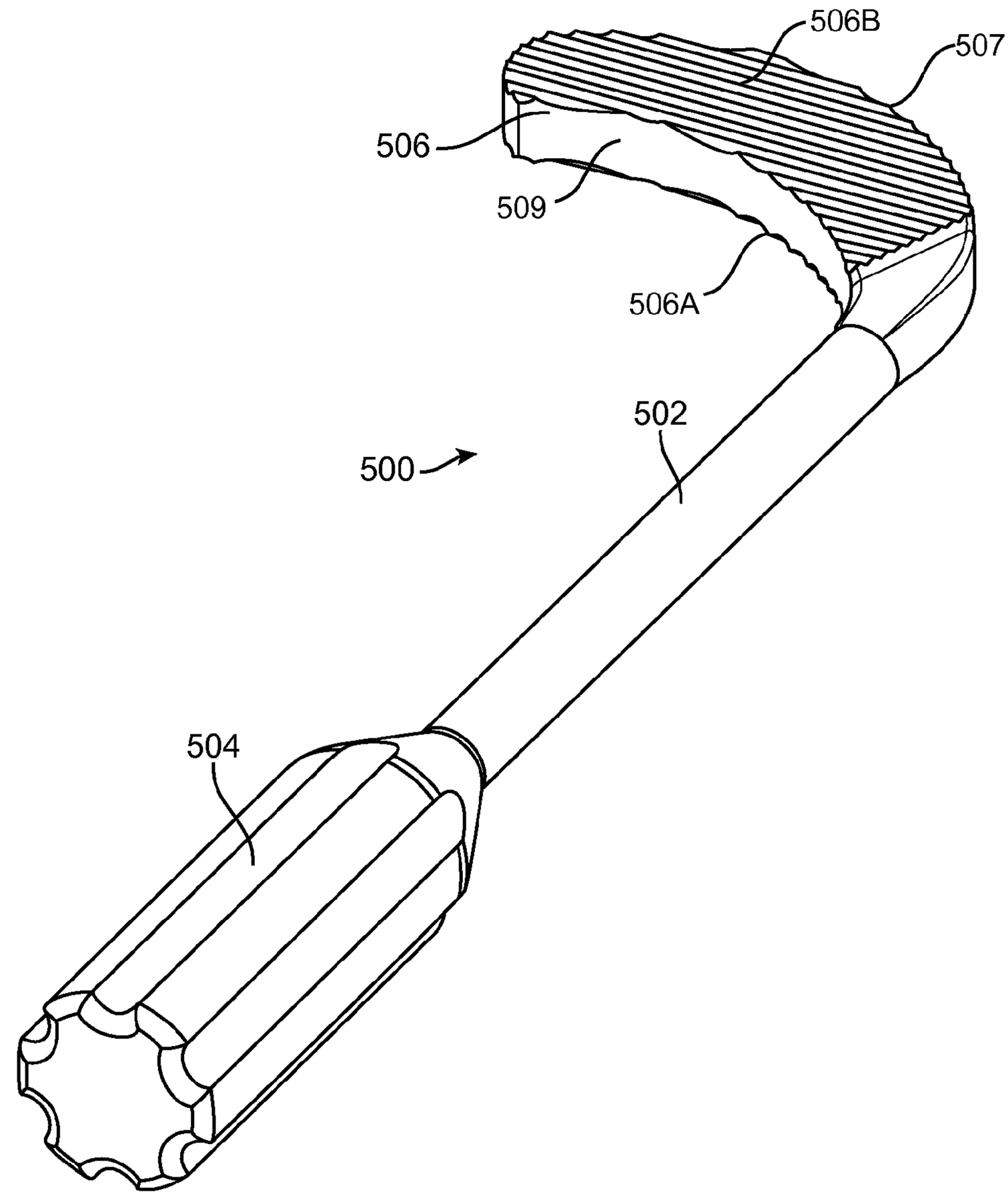

FIG. 15A

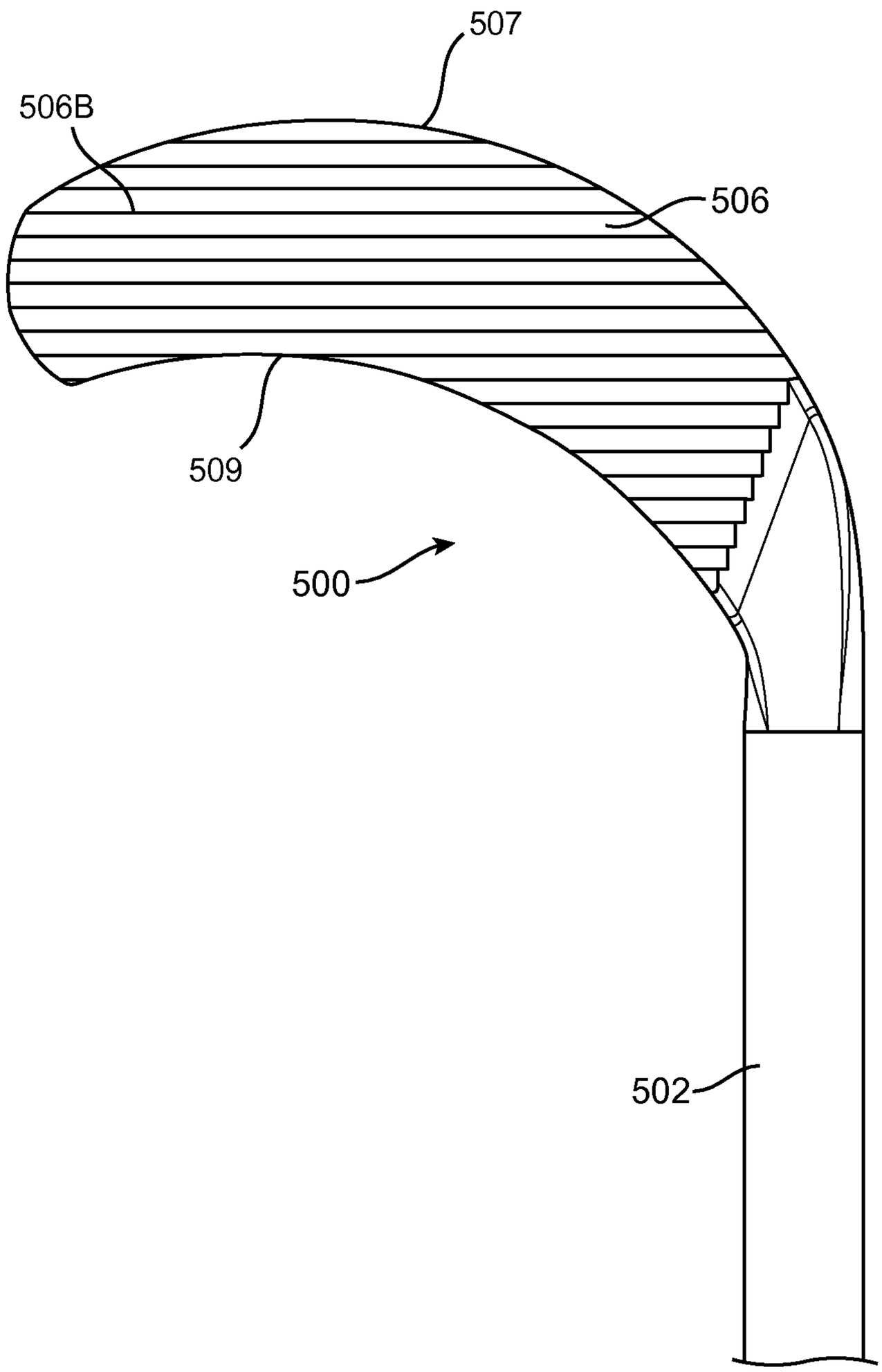

FIG. 15B

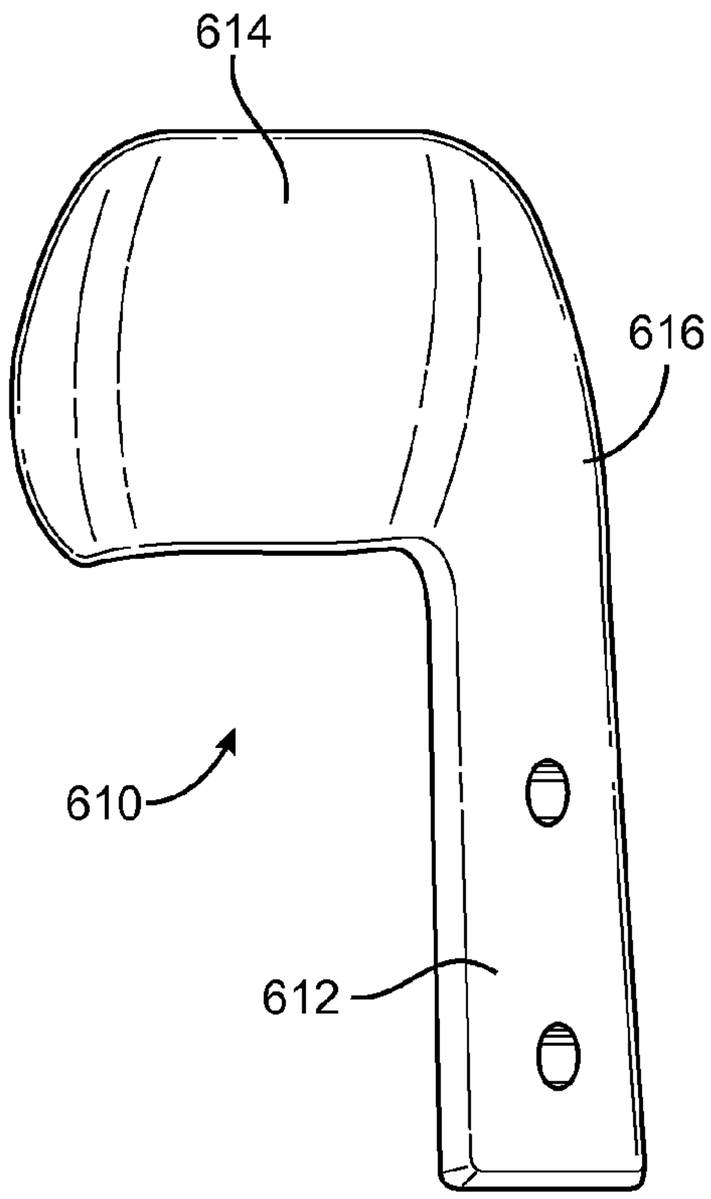

FIG. 16

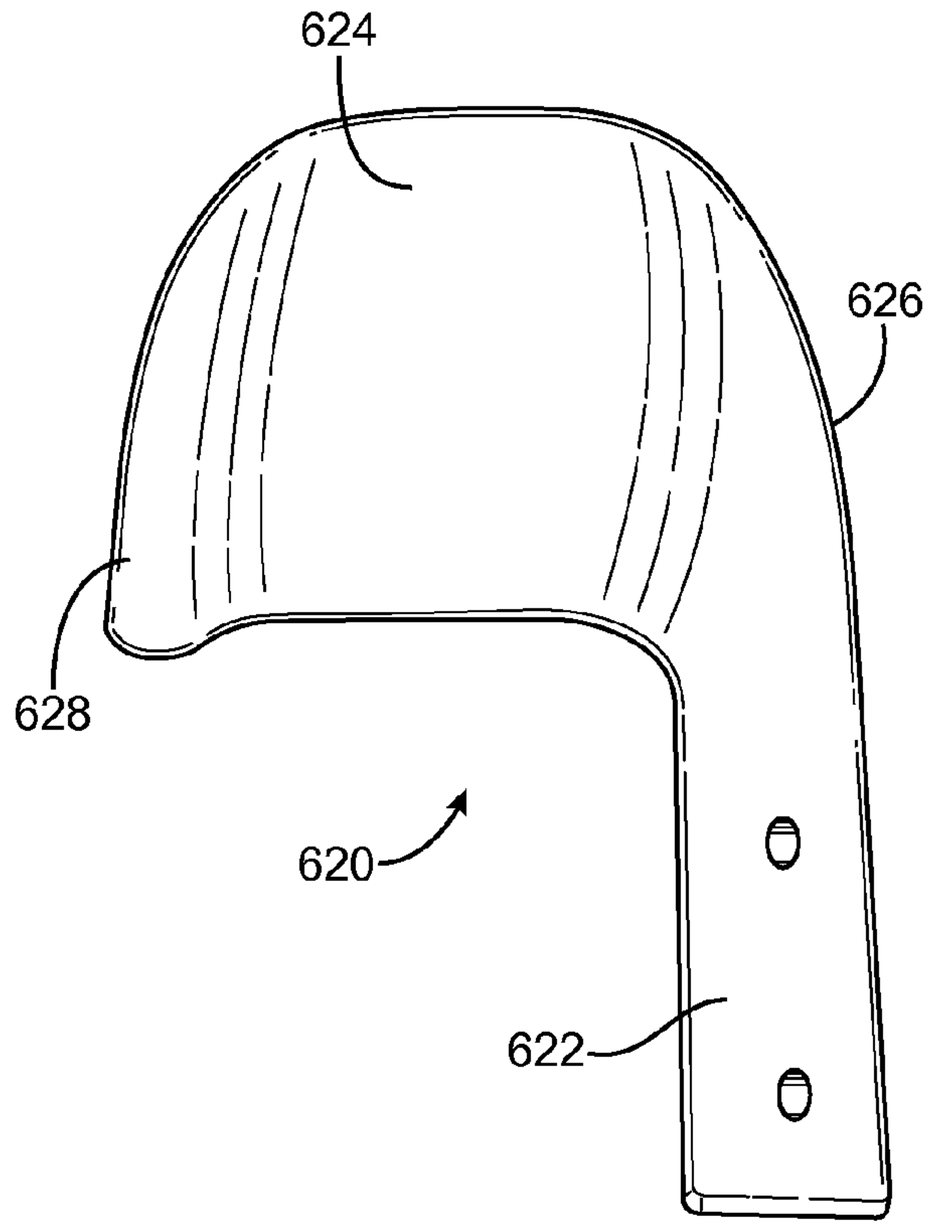

FIG. 17

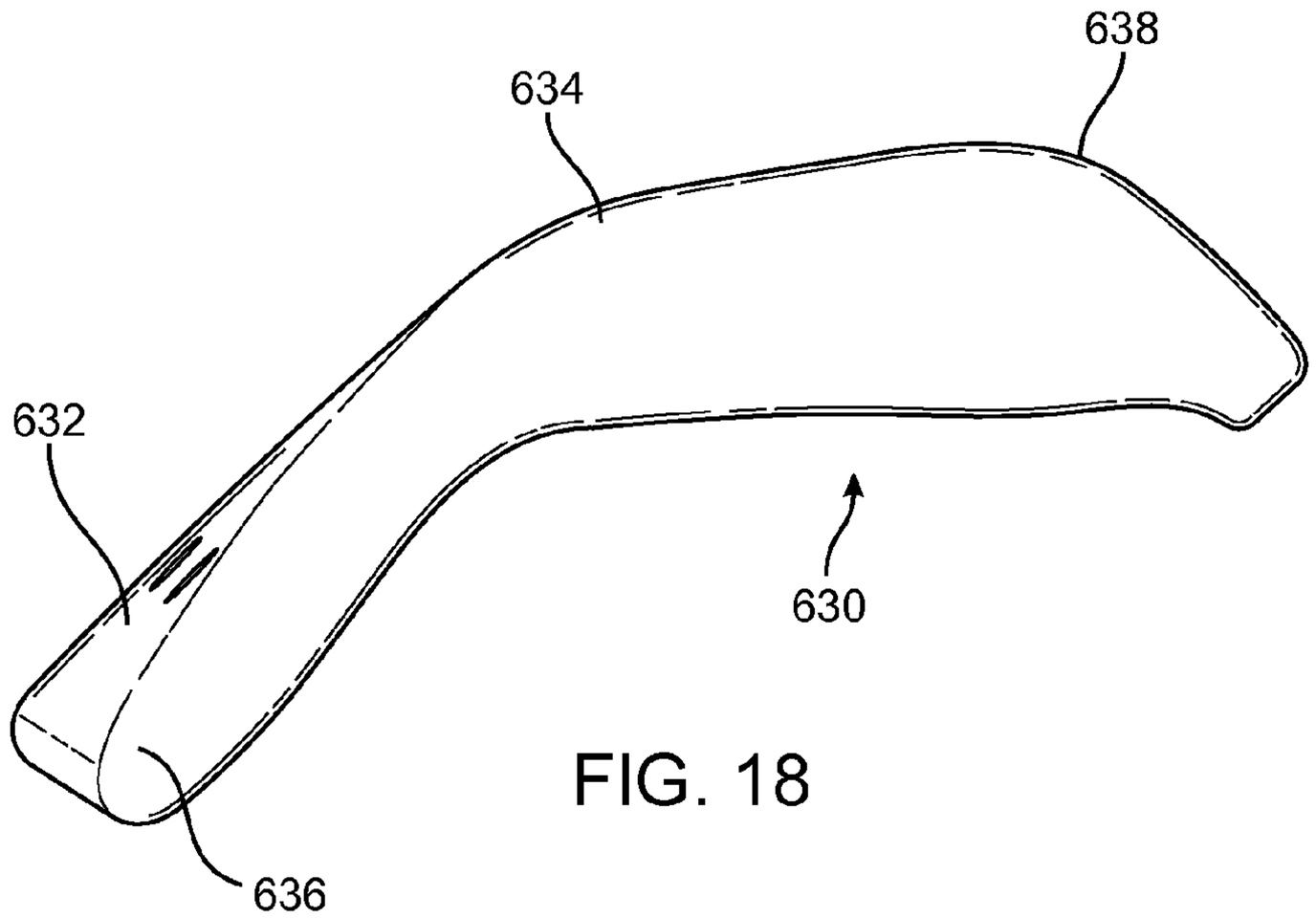

FIG. 18

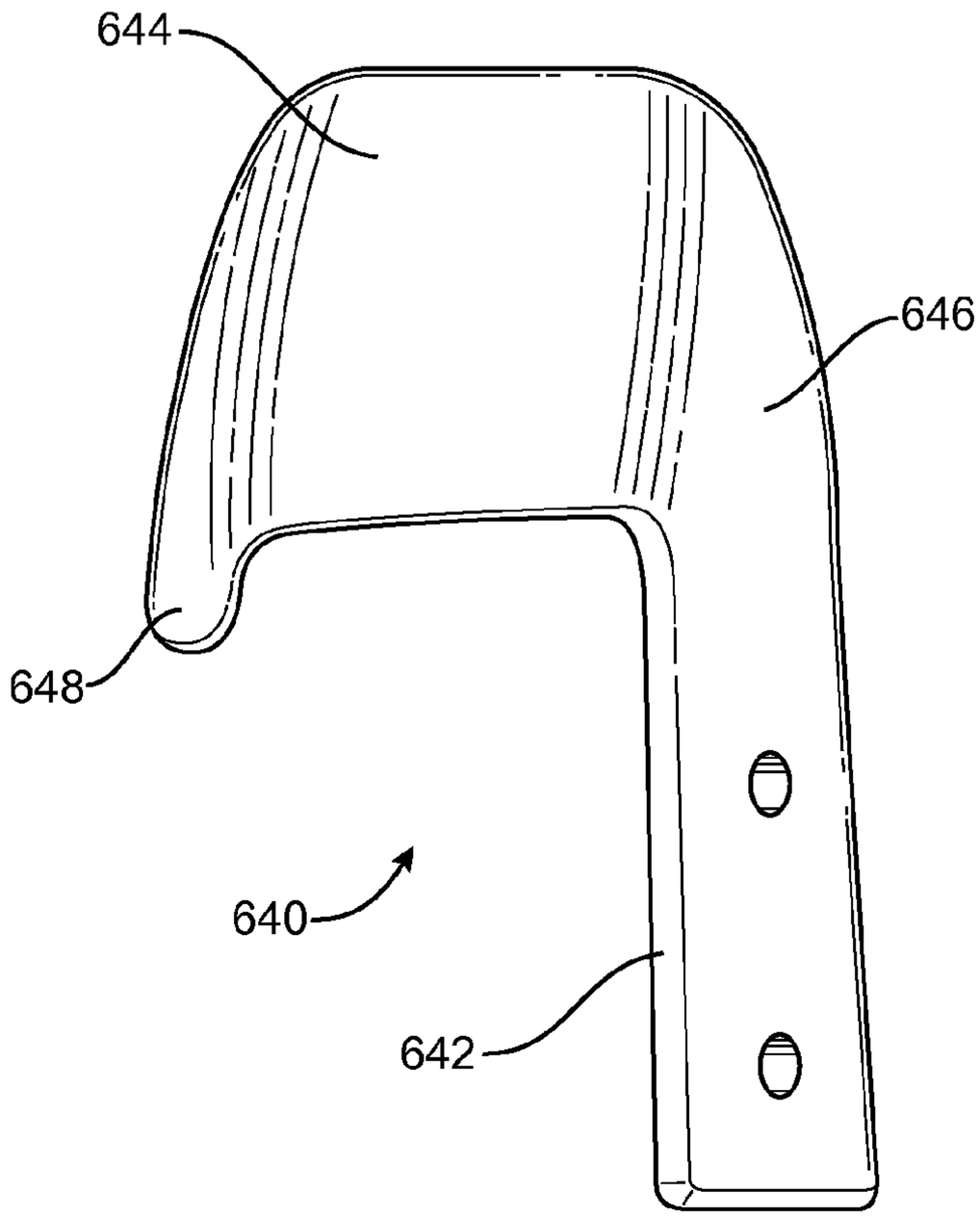

FIG. 19

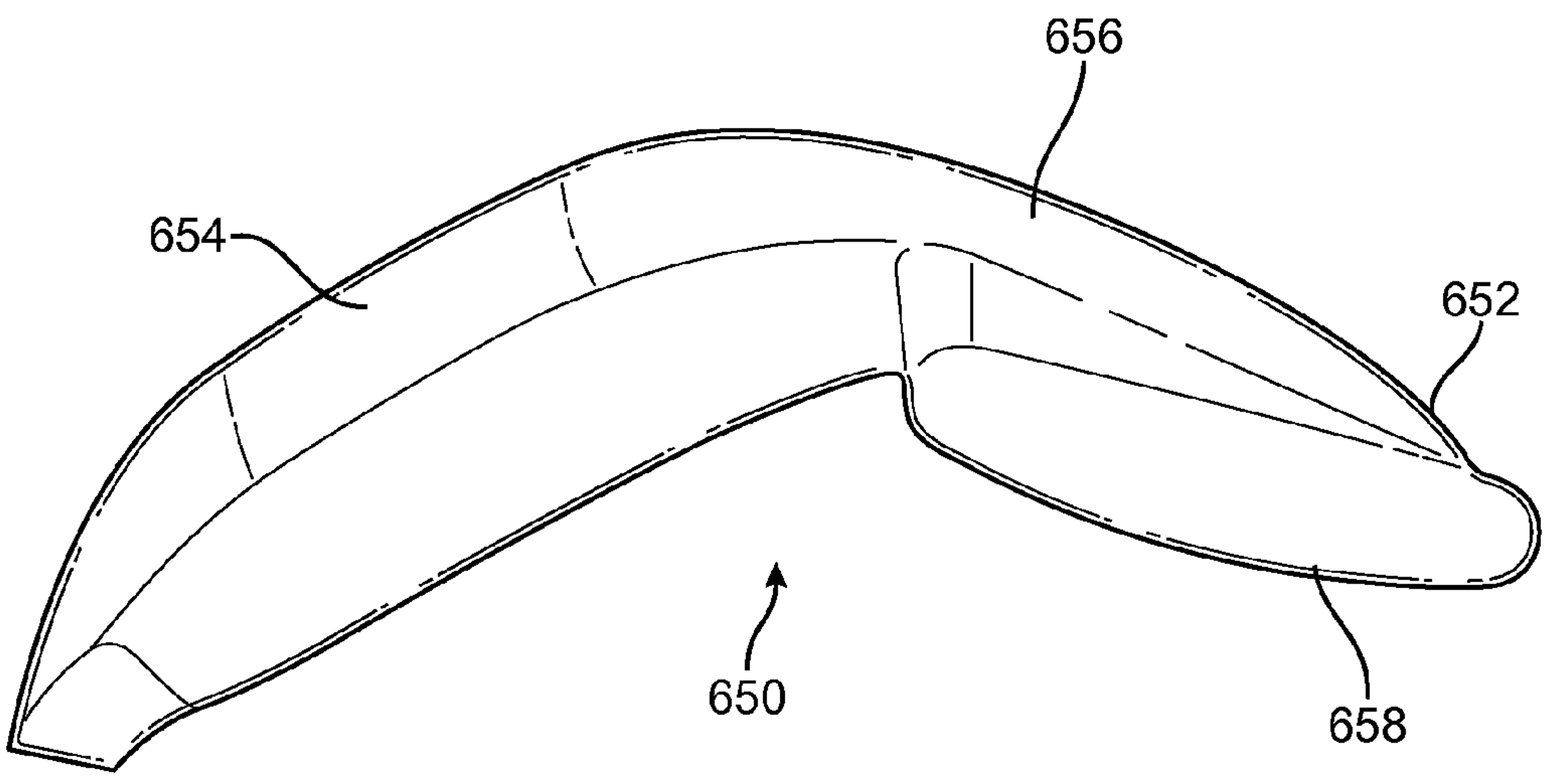

FIG. 20

APPARATUS AND METHODS FOR TREATMENT OF PATELLOFEMORAL CONDITIONS

RELATED APPLICATION DATA

This application claims the benefit of priority of U.S. Provisional Patent Application Ser. No. 61/951,469, filed Mar. 11, 2014, and U.S. Provisional Patent Application Ser. No. 61/951,470, filed Mar. 11, 2014, both of which are entitled "Apparatus and Methods for Treatment of Patellofemoral Conditions"; this application is also a continuation-in-part of U.S. Nonprovisional patent application Ser. No. 13/002,829, filed Aug. 27, 2010, and titled "Method and Apparatus for Force Redistribution in Articular Joints"; which application is a 371 of International Patent Application No. PCT/US10/46996, filed Aug. 27, 2010, and titled "Method and Apparatus for Force Redistribution in Articular Joints", which claims the benefit of priority of U.S. Provisional Patent Application Ser. No. 61/237,518, filed Aug. 27, 2009, and U.S. Provisional Patent Application Ser. No. 61/288,692, filed Dec. 21, 2009, each entitled "Method and Apparatus for Force Redistribution in Articular Joints"; this application is also a continuation-in-part of U.S. Nonprovisional patent application Ser. No. 13/843,128, filed Mar. 15, 2013, and titled "Method and Apparatus for Altering Biomechanics of Articular Joints"; which application claims priority to U.S. Provisional Patent Application Ser. No. 61/620,756 filed on Apr. 5, 2012 and U.S. Provisional Patent Application Ser. No. 61/695,406 filed on Aug. 31, 2012; and which application is also a continuation-in-part of U.S. Nonprovisional patent application Ser. No. 12/870,462, filed on Aug. 27, 2010 (now U.S. Pat. No. 8,597,362 issued Dec. 3, 2013), which claims priority to U.S. Provisional Patent Application Ser. No. 61/237,518, filed Aug. 27, 2009, and U.S. Provisional Patent Application Ser. No. 61/288,692, filed Dec. 21, 2009. Each of the foregoing applications is incorporated by reference herein in its entirety.

The present invention generally relates to the field of orthopedic prostheses and procedures. In particular, the present invention is directed to apparatus and methods for treatment of patellofemoral conditions.

BACKGROUND

As the present invention is directed to apparatus and methods for treatment of patellofemoral conditions, a basic discussion of the anatomy of the knee with a focus on the patellofemoral structures may assist in describing the various embodiments of the invention. FIG. **1** is a schematic portrayal in side view of a human knee. The bones of the knee joint comprise the femur (F), tibia (T), and patella (P). The fibula (fib) is another bone in the lower leg that attaches to the tibia. As primarily relevant to embodiments of the present invention, connective tissues of the knee joint include the patellar tendon (PT) and the quadriceps tendon (QT). The patellar tendon is also referred to as the patellar ligament as its primary function is to create a connection between bones, i.e., the tibia and patella. The patellar tendon extends from the caudal (lower) extent of the patella to an attachment point on the tibial tuberosity (TT) of the tibia. The tibial tuberosity comprises a raised area on the anterior (forward) aspect of the tibia, caudally positioned (toward the foot or lower) with respect to the cranial (upper) end of the tibia. The quadriceps tendon extends from the cranial extent of the patella and joins with the quadriceps-femoris muscle.

The knee is a synovial joint, meaning that the bones are not directly joined but are surrounded by dense connective tissues forming an articular capsule (C) lined by a synovial membrane. The capsule defines a synovial cavity or intracapsular space (IC) that contains the articular cartilage of the joint (not shown) and synovial fluid that acts to reduce friction between the articular cartilages. The approximate extent of the capsule is indicated in FIG. **1** by dashed lines (C'). The quadriceps and patellar tendons lie outside the capsule. Also outside the capsule is the infrapatellar fat pad (FP). The fat pad is situated posteriorly and caudally with respect to the patella and joins with the patellar tendon on its posterior side over much of its length. The knee joint also includes a number of bursae to protect and facilitate movement between various bony and soft tissues. One of these bursae is the deep infrapatellar bursa (B), which allows for movement of the patellar tendon over the tibia. This bursa is positioned between the upper part of the tibia and the patellar tendon and lies in a pocket outside of the infrapatellar fat pad.

Because of the importance of the capsule in protecting and lubricating the articular cartilage, it is usually preferable, whenever possible in a knee intervention, to avoid penetrating the capsule. Because of the role of the infrapatellar fat pad in protecting the knee, it is also usually preferable to avoid dissecting the fat pad during knee interventions. Previously, removal of all or part of the fat pad was common in arthroscopic procedures in order to permit better visibility for the surgeon. However, it has been discovered that damage to the fat pad can lead to scarring, which can be painful and even crippling in some patients.

Treatments for various patellofemoral pathologies such as patellofemoral pain and patellofemoral osteoarthritis (PFOA) have been increasingly investigated. One early treatment, which involves anteriorization of the patellar tendon by a relatively invasive surgical procedure, was devised by Dr. Paul Maquet in the early 1960s. See, P. Maquet, 30 Revue Du Rhumatisme, No. 12, December 1963, pp. 779-783, "Biomechanical Treatment of Patellofemoral Osteoarthritis, Advancement of the Patellar Tendon" (translated title). In this procedure, an iliac bone autograft is implanted under the patellar tendon to relieve pressure in the patellofemoral space. Later Dr. Maquet evolved his technique to cut the tibial tuberosity away from the tibia and reposition it. This became known as the Maquet Osteotomy, which has been performed on tens of thousands of patients over the years with positive results. See, e.g, Maquet, Biomechanics of the Knee, pp. 134-143 (pub. Springer-Verlag 1976). However, the Maquet Osteotomy is a highly invasive procedure, which carries with it all of the risks and costs associated with highly invasive orthopedic surgeries.

FIG. **2** is a schematic illustration of a relatively square bone implant **2** of the type proposed by Dr. Maquet implanted on the tibia (T) under the patellar tendon (PT). The patellar tendon is attached cranially to a caudal portion of the patella, and caudally to the tibia at the Tibial Tuberosity (TT). The natural line of action of the patella tendon would be generally along a line (L) extending between the two attachment points. Placing the bone implant **2** under the patellar tendon moves the patellar tendon anteriorly between its two attachment points and thus alters the line of action with respect to the patella. The new line of action (L_1), oriented more away from the patellofemoral space can reduce the pressure on that space. Said another way, anteriorizing the patellar tendon renders the angle between the

patellar tendon and the quadriceps tendon more obtuse, reducing the resultant force pressing the patella against the femur.

However, the success of such a procedure may depend heavily on the configuration of the implant used. If the anterior, tissue-engaging surface of the implant is roughly perpendicular to the caudal face of the implant and/or parallel to the underlying surface of the tibia, it displaces the patellar tendon relatively directly anteriorly (perpendicular to the tibial surface) and creates an abrupt step at the caudal edge of the implant, which can produce a number of complications. First is the creation of an unsightly bump on the knee. This is not merely a cosmetic problem, as the bump may catch on clothing or other, harder objects that could cause bruising or injury in the course of daily activity. Second, such an implant could be extremely uncomfortable in certain common positions. For example, if a patient with such an implant were to kneel on that knee, all of the load would be placed on that implant, which could be painful and also damaging to the patellar tendon.

A third possible complication arises from the fact that an implant shaped such as implant **2** also pulls the patella caudally, creating an undesirable misalignment. This condition is referred to as "Patella Infera" or "Patella Baja". The symptoms of this misalignment can include pain on quadriceps contraction, inadequate quadriceps contraction, swelling, edema, joint stiffness, limited joint motion and limited patellar mobility.

Further, it may be desirable to maximize the area of the posterior surface of the implant that lies against the bone in order to spread the forces on the implant over as wide an area as possible. And, in order to minimize Patella Baja, it may be desirable to engage the patellar tendon as far cranially as possible without interfering with the patella or other tissues during knee movement. Yet, the space in which the implant is to be located, between the tibial tuberosity and the fat pad, bursa, and/or capsular tissues, is extremely limited. If the posterior surface of the implant extends too far cranially along the bone surface it may interfere with the fat pad, bursa, or joint capsule, causing pain or other complications. What is needed, therefore, are devices and methods for relieving patella-femoral pain due to osteoarthritis or other conditions that overcome the foregoing challenges.

SUMMARY OF THE DISCLOSURE

In one implementation, the present disclosure is directed to a prosthesis for treating disorders of the knee in the patellofemoral compartment of the knee. The prosthesis includes a fixation portion configured to be mounted to the tibia proximate the upper tibial extremity and medially or laterally of the tibial tuberosity, a spanning section configured and dimensioned to extend cranially and laterally or medially from the fixation portion in a direction towards the tibial mid-line, and a displacement portion configured and dimensioned to (i) extend from the spanning section further laterally or medially under patellar tendon and in engagement therewith, and (ii) displace the patellar tendon anteriorly sufficiently to alter the location, angle or magnitude of forces exerted thereby on the patella so as to achieve a therapeutic effect in patellofemoral compartment of the knee.

In another implementation, the present disclosure is directed to a prosthesis for treating disorders of the knee in the patellofemoral compartment of the knee. The prosthesis includes a fixation portion configured to be mounted to the tibia proximate the upper tibial extremity and medially or laterally of the tibial tuberosity, a spanning section configured and dimensioned to extend cranially and laterally or medially from the fixation portion in a direction towards the tibial mid-line, a displacement portion configured and dimensioned to extend from the spanning section further laterally or medially under the patellar tendon, defining a space between at least a part of the displacement portion and tibial surface, to displace the patellar tendon at least anteriorly from a normal, anatomical path; and a supplemental support element with a bone engaging surface disposed at an end of the displacement portion opposite the spanning section, the displacement portion being further configured and dimensioned to dispose the bone engaging surface against the tibial surface when the fixation portion is mounted to the tibia.

In yet another implementation, the present disclosure is directed to a prosthesis for repositioning a target tissue, the target tissue comprising a connective tissue or muscle relative to a bone on which the target tissue acts. The prosthesis includes a fixation portion having one or more fixation features configured to receive fixation elements for securing the implant to the bone, and a displacement portion having a first end connected to the fixation portion and a free end opposite the first end, the displacement portion having a bearing surface configured to atraumatically engage and reposition the target tissue relative to the bone wherein the displacement portion has a base portion configured to engage the bone and a cantilevered portion extending from the base portion to the free end, the cantilevered portion being configured to be spaced apart from bone when the base portion is engaging the bone.

In still another implementation, the present disclosure is directed to a femorally mountable prosthesis for treating patellofemoral osteoarthritis or patellar maltracking. The prosthesis includes a fixation portion including one or more fixation holes, the fixation portion being generally straight and elongated, and configured for fixation to the femur at least approximately aligned with the femoral shaft on a lateral, medial or anterior-medial/lateral side of the femur, and cranially with respect to the patella; a displacement portion configured and dimensioned to (i) be positioned under the quadriceps tendon cranially with respect the attachment point of the quadriceps tendon to the patella, and (ii) to atraumatically engage and displace the quadriceps tendon anteriorly relative to the femur to increase space in the patellofemoral area; and a spanning section interconnecting the fixation portion and the displacement portion, the spanning section configured and dimensioned to position the displacement portion to engage and displace the quadriceps tendon.

In still yet another implementation, the present disclosure is directed to an instrument for reshaping a bone surface. The instrument includes a shaft having proximal and distal ends arranged along a longitudinal axis and an elongated file element coupled to the distal end of the shaft and extending in a direction transverse to the shaft and longitudinal axis, the file element having a curvature about a second axis transverse to the longitudinal axis and having anterior and posterior surfaces lying in respective planes intersected by the second axis, at least one of the anterior and posterior surfaces having features configured to reshape bone when the file is moved in engagement therewith.

In another implementation, the present disclosure is directed to a method for treating patellofemoral osteoarthritis or patellar maltracking. The method includes mounting a prosthesis on the tibia at a fixation site outside of the knee joint capsule proximate the upper tibial extremity and medi-

ally or laterally of the tibial tuberosity without rupturing the capsule and with a portion of the prosthesis extending under the patellar tendon to displace the patellar tendon from a normal, anatomical path in at least an anterior direction and without disrupting the attachment of the infrapatellar fat pad to the tibia and without dissecting the infrapatellar fat pad.

In yet another implementation, the present disclosure is directed to a method of implanting a device on the tibia. The method includes inserting a file element through an incision on a medial or lateral side of the tibia such that the file element extends in a medial-lateral direction across an anterior surface of the tibia cranially of the tibial tuberosity and a handle coupled to the file element extends in a cranial-caudal direction along the tibia outside the incision; moving the handle such that file element reshapes the anterior surface of the tibia to a first shape; placing an implant through the incision and positioning a base portion of the implant in engagement with the anterior surface of the tibia with a displacement portion of the implant under the patellar tendon, the base portion having a posterior surface with a shape complementary to the first shape; and securing the implant to the tibia.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating the invention, the drawings show aspects of one or more embodiments of the invention. However, it should be understood that the present invention is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIG. **1** is a schematic diagram illustrating anatomical features of a human knee joint in a side view;

FIG. **2** is a schematic representation of an implant in accordance with early work of Dr. Paul Maquet;

FIG. **3** is a schematic illustration of an implant according to one disclosed embodiment;

FIG. **3**A is a combined view with the embodiment shown in FIG. **3** superimposed over the implant shown in FIG. **2**;

FIGS. **4**A and **4**B are diagrams illustrating profiles for tissue bearing surfaces in accordance with disclosed embodiments;

FIGS. **5**A, **5**B and **5**C are a series of schematic illustrations showing disclosed embodiments implanted on the tibia at the knee, with the knee at flexion angles of about 0°, 45° and 90°, respectively;

FIGS. **6**A and **6**B illustrate another embodiment disclosed by the inventors in an incorporated application;

FIGS. **7**A, **7**B, **7**C, **7**D, **7**E, **7**F and **7**G illustrate features of another embodiment disclosed by the present inventors in another incorporated application;

FIGS. **8**A, **8**B and **8**C show alternative embodiments, wherein FIG. **8**A is a schematic illustration of an implant on the tibia, FIG. **8**B is a perspective view of the implant, and FIG. **8**C illustrates a further alternative, as would be seen along line C-C in FIG. **8**B;

FIGS. **9**A and **9**B show further alternative embodiments, wherein FIG. **9**A is a schematic illustration of the implant on the tibia and FIG. **9**B is a cross-sectional view through section A-A of FIG. **9**A;

FIG. **9**C illustrates another alternative embodiment, again in a view through section A-A of FIG. **9**A;

FIG. **9**D is a cross-sectional view through section D-D of FIG. **9**B;

FIG. **10** is a schematic diagram of a human knee in side view illustrating positioning of an implant according to another disclosed embodiment;

FIGS. **11**A, **11**B and **11**C are perspective views of further alternative embodiments employing supplemental fixation/support means;

FIG. **11**D is a schematic illustration of an embodiment such as shown in FIG. **11**C in place on a portion of the tibia;

FIGS. **12**A, **12**B, **12**C, **12**D and **12**E are various views of yet another alternative embodiment employing a separate fixation base member;

FIG. **12**F is a schematic illustration of a further alternative embodiment, also employing a separate fixation base in place on a portion of the tibia;

FIGS. **13**A, **13**B, **13**C, **13**D and **13**E are views of other alternative embodiments having differently shaped fixation portions;

FIGS. **14**A and **14**B are schematic illustrations of further alternative embodiments adapted for femoral fixation;

FIGS. **15**A and **15**B are views of an embodiment of disclosed instrumentation useful in procedures for placement of implants disclosed herein;

FIG. **16** is a drawing of another alternative embodiment viewed from the anterior aspect of an implant with a configuration generally as described herein;

FIG. **17** is a drawing of another alternative embodiment viewed from the anterior aspect of an alternative implant including features similar to the embodiment shown in FIGS. **9**A and **9**B;

FIG. **18** is a drawing of another alternative embodiment viewed from a cranial aspect of another alternative implant with a displacement portion having an increasing thickness;

FIG. **19** is a drawing of another alternative embodiment viewed from an anterior aspect of a further alternative implant including features similar to the embodiments shown in FIGS. **11**B and **11**C; and

FIG. **20** is a drawing of another alternative embodiment viewed from a caudal aspect of yet another alternative implant with features to facilitate positioning prior to fixation;

DETAILED DESCRIPTION

Embodiments of the present invention employ an improved implant geometry with an appropriately curved cross-section to address drawbacks of some prior devices and procedures, such as an unsightly and uncomfortable bump, concerns about tissue damage, and the caudal movement of the patella as previously discussed. Other embodiments of the present invention employ supplemental support/fixation means and specially shaped fixation portions to facilitate implantation, increase fixation security and resist torqueing forces. Further embodiments of the present invention encompass less invasive methods for treatment of patellofemoral conditions, including employing implant embodiments disclosed herein.

The present inventors have disclosed implants for treating PFOA in United States Patent Publication US 2011/0213466, entitled "METHOD AND APPARATUS FOR FORCE REDISTRIBUTION IN ARTICULAR JOINTS," and, more recently in United States Patent Publication US 2013/0211521, entitled "METHOD AND APPARATUS FOR ALTERING BIOMECHANICS OF ARTICULAR JOINTS," each of which is incorporated herein by reference in their entirety. In certain embodiments therein disclosed, an implant portion is inserted underneath the patellar tendon, just cranial to the attachment of the patellar tendon to the tibial tuberosity. This implant portion displaces the patellar tendon anteriorly, flattening the angle between the patellar tendon and the quadriceps tendon. This change in angle

reduces the resultant pressure of the patella against the femur, reducing patellar pain and patellofemoral cartilage wear. The implant may also improve patellar tracking, or shift the location, angle or loading of the patella against the femur.

FIG. **3** schematically illustrates features of the embodiments in this disclosure. The schematic side view of FIG. **3** helps to illustrate the positioning and curved shape of the bearing surface **11** and displacement portion **12** of embodiments disclosed herein. The bearing surface **11** is the surface of the displacement portion **12** in contact with the patellar tendon. Line L_2 shows the approximate line of action of the patellar tendon after repositioning over displacement portion **12**. To simplify FIG. **3** for discussion purposes, fixation means and other implant structures such as the fixation portion and spanning section discussed in more detail below are not called out. The various fixation and support structures discussed below facilitate the cantilevering of displacement portion to better accommodate soft tissue structures while properly positioning the bearing surface as discussed in more detail below.

In general, implants according to embodiments of the invention will be configured and dimensioned to displace the tissue targeted for treatment by between about 5 mm to about 30 mm from the natural, anatomical tissue path. In some embodiments, the displacement will be greater than about 10 mm. Overall displacement amounts can be set through a combination of shape and size of the fixation portion, spanning section and displacement portion of the implant as previously described. Working within those parameters, it has been discovered that by shaping the bearing surface at least approximately as a quarter-circle in cross-section with a minimum radius of about 8 mm, caudal biasing of the patella can be reduced. Further flattening the curvature of the bearing surface, by increasing radius, or making the surface more oval, elliptical, hyperbolic, or of another complex shape, can further reduce caudal biasing, but space limitation arising from the anatomy and need for a minimum displacement to achieve therapeutic effects may limit the amount of such flattening that may be applied to the implant. In addition, the displacement portion and/or bearing surface may be shaped and dimensioned to provide different magnitudes of displacement at different points along the surface such that the tissue is displaced different amounts at different joint positions, e.g. at different points in the gait cycle. As used herein, "therapeutic effect" means an effect on a treated joint that reduces forces acting on the articular surfaces, reduces wear, lessens pain or provides another positive outcome for the patient whether across the joint as a whole or in particular compartments of the knee. "Therapeutic effect," however, does not imply, and should not be understood as requiring, any specific, quantified outcome other than as stated above.

As shown in FIG. **4**A, for a bearing surface (B) with a depth and length of 1 mm in each dimension, the patella is pulled caudally by only about (Π/2−1) or 0.57 millimeters. In an alternative embodiment, the bearing surface curve may be flattened even further with a length of about 2 mm while maintaining the 1 mm depth, as shown in FIG. **4**B. In this embodiment, the caudal displacement of the patella would be less than half of the anterior displacement. The generally elliptical shape of the bearing surface causes such an implant to extend generally twice as far cranially as it does anteriorly and thus would pull the patella caudally by an amount approximately equal to 0.42 times the anterior displacement. Caudal displacement with an elliptically shaped bearing surface may be estimated based on a corresponding elliptical circumference. For example, using an "ellipse calculator" (e.g. as available online at http://www.cleavebooks.co.uk/scol/callipse.htm) and selecting a major axis of 4 and a minor axis of 2, a circumference of 9.69 can be determined. Dividing the circumference by 4 gives 2.422 (approximately one quarter of the elliptical circumference corresponding to the overall length of the bearing surface). With this information, it may be estimated that a curved bearing surface with a cranial-caudal length of 2 cm and an anteriorization of 1 cm will pull the patellar tendon caudally approximately 0.42 cm.

A geometry as described in the preceding paragraphs should dramatically reduce the complications caused by patella baja from square or steeply profiled implants. For example, a prior art implant with a square cross-section, such as shown in FIG. **2**, would pull the patella caudally by approximately one millimeter for each millimeter of anteriorization; about twice the amount of caudal displacement created by embodiments disclosed herein for the same amount of anteriorization.

In certain embodiments, the bearing surface **11** will be positioned with its outer most point (apogee) at a perpendicular distance from the surface of the tibia below it of about 0.3-3 cm, or more typically about 0.5-1.5 cm for an implant configured to treat an average adult knee. The width of the bearing surface in the generally cranial-caudal direction will be about 0.5-3.0 cm, or more typically about 1.0-2.5 cm. While distance from the tibia to the apogee of the bearing surface can equal the bearing surface width, in some embodiments the width will be greater than that distance, about 1.1-3.0 times greater, or more typically about 1.5-2.0 times greater. Further alternative embodiments may employ bearing surfaces with compound curvatures comprising elements of FIGS. **4**A and **4**B as previously discussed.

A further physiologic benefit to an implant with the curved geometry as described is that the forces pressing the patella against the femur are highest when the knee is bent, such as when a person is climbing stairs. As shown in FIG. **3**A, where an embodiment of the present invention is superimposed over a prior implant, the shape of the present invention is more effective in flattening the angle between the patellar tendon and the quadriceps tendon when the knee is bent. It also reduces the focal stress on the sharply angled portion of the patellar tendon caused by such prior implants, especially when the leg is straight. The extreme caudal positioning of the prior implant **2** is indicated at (A) in FIG. **3**A.

The beneficial effect of embodiments of the present invention as related to knee flexion are further illustrated in FIGS. **5**A-C. From these figures, it can be seen that the angle α of anteriorization is increased from the natural line of the patella tendon from α_1 with the knee fully extended, to α_2 at partial flexion, up to α_3 at 90° flexion in FIG. **5**C, where $\alpha_1<\alpha_2<\alpha_3$. The unloading provided by the implant thus increases with knee flexion, providing the greatest relief when the patella is maximally loaded.

Further embodiments are shown in FIGS. **6**A and **6**B (corresponding to FIGS. **24** and **25**, respectively, of the present inventors' first incorporated publication above), and FIGS. **7**A-F (corresponding to FIGS. **8** and **9**A-E, respectively, of the present inventors' second incorporated publication above). In the embodiments of FIGS. **6**A and **6**B, implant **210** includes a support member **212** and bearing member **214**. The support and bearing members are functionally divided into displacement portion **216**, spanning section **218** and fixation portion **220**. The displacement

portion, with the bearing member is partly cantilevered over the tibia so that a portion of the fat pad may be received thereunder.

FIGS. **7**A-G depict an exemplary prototype of implant **300** for treating patellofemoral osteoarthritis and/or patellar maltracking for the right knee. Implant **300** has a fixation portion **312** having one or more holes **315** for receiving screws for anchoring the implant to bone. Fixation portion **312** is generally straight and elongated, being configured for positioning in general alignment with the tibial shaft on the medial or anterior-medial side of the tibia. Bone engaging surface **313** is provided on the bone facing side of the fixation portion. Holes **315** are preferably positioned in approximate alignment with a longitudinal centerline of fixation portion **312**.

Displacement portion **314**, is configured and dimensioned to be positioned under the patellar tendon caudally separated from the insertion point of the tendon in the tibia. The displacement portion **314** is configured to atraumatically engage the tendon and displace it anteriorly relative to the tibia. The displacement portion **314** has a length in the lateral-medial direction generally selected to accommodate the full width of the tendon so that the tendon remains engaged along its entire width as it slides on the displacement portion. Displacement portion **314** preferably has a convex curvature on its outer tissue-engaging surface (bearing surface **309**), preferably being curved at least around an axis generally parallel to the tibial shaft, usually being curved also around an axis perpendicular to the tibial shaft, and more preferably being spherical or partially spherical. Displacement portion **314** has a width in the caudal-cranial direction is selected so that it does not interfere with the patella or engage the insertion point of the tendon, typically being less than its length. A spanning section **316** interconnects fixation portion **312** and displacement portion **314**. Spanning section **316**, in the embodiment illustrated, extends cranially and laterally from fixation portion **312** to displacement portion **314**, forming a curve of about 90° about a dorsal-ventral axis. Where fixation portion **312** is configured for attachment to a more medial aspect of the tibia, spanning section **316** will extend ventrally as well as cranially and laterally from fixation portion **312**, preferably being curved about an axis generally parallel to the tibial shaft. Displacement portion **314** appropriately displaces the patellar tendon in cooperation with the fixation portion **312** and spanning section **316**.

Displacement of the target tissue can be altered by changing the length, curvature and angle of the spanning section among other features. For example, the angle α between the displacement portion **314** and the fixation portion **312** (as measured at the intersection of the center line axes of the two portions in the top view of the implant in FIG. **7**B) may range from about 80 degrees to 135 degrees, more specifically from about 85 degrees to 120 degrees, and in some embodiments about 90 degrees to 110 degrees.

The width W_1 of the fixation portion **312** (FIG. **7**C) typically will be large enough to span a substantial portion of the width of the tibia and to accommodate one or more screw holes of sufficient size, ranging from about 10 mm to 25 mm. In some embodiments, width W_1 may be about 12 mm to 20 mm, and in other embodiments about 14 mm to 18 mm. The length L_1 of the fixation portion **312** will be selected to accommodate a sufficient number of screw holes in the cranial-caudal direction along the tibia, usually at least two and in some embodiments up to five or more, and may range from about 20 mm to 50 mm, more specifically about 25 mm to 45 mm, and in some embodiments about 30 mm to 40 mm.

The width W_2 (generally cranial-caudal direction) of the displacement portion **314** (FIG. **7**B) is generally selected to provide a broad area of contact with the tendon to spread the force and reduce wear, while not interfering with the patella or the tendon insertion point throughout the full range of joint motion. Width W_2 may thus range from about 10 mm to 25 mm, more specifically about 12 mm to 20 mm, and in some embodiments about 14 mm to 18 mm. The length L_2 (generally medial-lateral direction) of the displacement portion **314** is selected so that the displacement portion extends under the full width of the tendon so that the entire width of the tendon remains in engagement and displaced the desired amount throughout the range of joint motion. Length L_2 may thus range from about 20 mm to 50 mm, more specifically about 25 mm to 45 mm, and in certain embodiments about 30 mm to 40 mm.

As best seen in FIGS. **7**E-G, implant **300** also includes a supporting section **320** extending along the caudal extent of displacement portion **314**, into spanning section **316** and merging into the bone engaging surface **313** of fixation portion **312**. As will be appreciated by persons of ordinary skill, contour line **322** illustrates the approximate extent of supporting section **320** from the displacement portion, through the spanning section and into the fixation portion.

Supporting section **320** rests on the surface of tibia between the tendon insertion point and the fat pad and/or capsular tissue. The cranial-caudal length of bone engaging surface **313**, i.e., the approximate distance from cranial most location of contour line **322** delineating the cranial extent of the supporting section, to the caudal end of fixation portion **312** is preferably greater than the distance from same point on contour line **322** to the cranial edge of displacement portion **314**. The appropriate distance ratios between these two regions increases the moment arm resisting torqueing force applied by the patellar tendon through the cantilevered displacement portion **314** to help fix the implant in place and resist loosening over time due to the cyclic torqueing forces applied by knee flexion and extension.

Displacement portion Height (H), shown in FIG. **7**G, is the perpendicular distance from the apogee of bearing surface **309** to the bone engaging surface **313**. Height (H) directly effects the amount of displacement of the tendon achievable with the implant. In general terms, the displacement distance will approximately equal Height (H) minus the normal anatomical distance between the patellar tendon and the tibial surface below it at the location of the displacement portion when implanted.

Implant depth D, along with the radius of curvature R_1 of the outer surface of displacement portion **314**, shown in FIG. **7**F, are selected to balance tendon displacement throughout the range of joint motion with the appropriate fixation location. Radius of curvature R_1 is usually 20-35 mm, more preferably 22-33 mm, and most preferably 25-30 mm. For average patient anatomy, an overall implant depth (D), shown in FIGS. **7**C and **7**F, as measured from the outermost surface of displacement portion **314** to the centerline of the screw holes in fixation portion **312**, would be in the range of 10-45 mm in order to provide target tissue displacements in the ranges cited hereinabove to achieve a therapeutic effect.

The inferior edge **304** of the spanning section **316** can also be curved to minimize or eliminate any contact with the medial edge of the patellar tendon. The superior surface edge **305** of the displacement portion **314** can be curved to allow for easy motion of the patellar tendon during flexion

as well as to vary the displacement of the patellar tendon during flexion by varying the region of the implant surface in contact with the tendon at higher flexion angles. In one exemplary embodiment, implant **300** is placed on the medial side of the distal tibia such that fixation portion **312** is substantially aligned with the tibial shaft, the spanning section **316** is positioned to minimize contact with the medial edge of the patellar tendon, and the displacement portion **314**, extending laterally from the spanning section, is substantially parallel to the tibial plateau.

A supporting section as generally described above may be incorporated into other embodiments disclosed herein to facilitate locating the fixation portion (and in particular bone screw site) at a distance from the area where displacement portion acts to allow for easier placement of the device, without a need to place fixation elements such as nails or screws under or close to the patellar tendon, the joint capsule or the infrapatellar fat pad. It also means that the displacement element can be appropriately rounded and smooth, without any surface roughness or disturbances due to fixation elements. And although the fixation portion is at a distance from the displacement portion, much of the force from the patellar tendon is transmitted through the supporting section directly onto the tibia behind it. Further, by extending the fixation portion **312** caudally down the tibia relative to the supporting section (and contour line **322**), the leverage applied by the fixation screws is increased so as to counter any tendency of the displacement portion to be tilted toward the tibia under the forces exerted by the patellar tendon.

Another alternative embodiment of the present invention is shown in FIGS. **8**A and **8**B. While typically it would be preferable to position the fixation portion more caudally to locate the fixation means such as screws more distant from the joint capsule and other sensitive structures of the joint, in some patients and in some clinical situations this may not be possible, or fixation adjacent to the displacement portion may have other advantages. In this embodiment, implant **20** may have a displacement portion **22** with a bearing surface **24**. The bearing surface may be curved as described above in connection with FIGS. **4**A and **4**B. The bearing surface also may be optionally provided with a concave groove or channel **25** extending in the cranial-caudal direction to assist in guiding the displaced tissue as it passes thereover. However, the same embodiment also may be provided without the channel. Implant **20** also may have a fixation portion **26** with a bottom surface having a slight concavity **27** in the cranial-caudal direction configured to be seated on the tibia just cranially of the tibial tuberosity. Fixation means **28** such as screw holes, spikes or bone ingrown facilitating elements may be included in fixation portion **26**. Persons of ordinary skill in the art will appreciate that the features of the concave groove or channel **25** and/or bottom surface concavity **27** may be employed with other embodiments as described herein and are not restricted to use with implant **20**.

As shown in FIG. **8**A, and as employed by other embodiments of the invention disclosed herein, displacement portion **22** includes a cantilevered portion **22**A extending in the cranial direction, forming an undercut region **22**B on the inferior (bone facing) side of cantilevered portion **22**A, cranially of fixation portion **26**. Cantilevered region **22**A is configured to extend cranially over the anterior surface of the tibia and the overlying fat pad such that the cranial edge of bearing surface **24** extends a distance X of about 5-30 mm, more preferably about 10-25 mm, and most preferably about 15-22 mm, from the cranial edge of fixation portion **26**. This facilitates engagement of bearing surface **24** with the patellar tendon as far in the cranial direction as possible without interfering with the patella or femur, while undercut region **22**B provides a space in which the fat pad, capsular ligaments or other soft tissues may reside. By engaging the patellar tendon further in the cranial direction, the displacement force applied to the patella has less of a caudal component, reducing "Patella Baja".

In another alternative, a cover member **21** may be provided as shown in FIG. **8**C to protect and retain the tendon when it is received in channel **25**. Cover **21** is securable over bearing surface **24**, such as with screws **23**.

A further alternative embodiment of the present invention is shown in FIGS. **9**A and **9**B. In this embodiment, implant **30** may have a displacement portion **32** with a bearing surface **34**. Bearing surface **34** also may be curved as described above in connection with FIGS. **4**A and **4**B. Displacement portion may be supported and positioned by spanning section **36**, which is in turn supported by fixation portion **38**. Spanning section **36** and displacement portion **32** may be configured and dimensioned to provide varying amounts of cantilever for the bearing surface **34**. Such a cantilever can provide clearance for the fat pad and/or other critical tissues behind the implant. Fixation means **39** such as screw holes, spikes or bone ingrown facilitating elements may be included in fixation portion **38**.

Referring to FIGS. **9**B and **9**D, it can be seen that displacement portion **32** can be provided with a concavity on the bone-facing posterior side of displacement portion **32** that spaces the displacement portion away from the tibial, forming a space (S) therebetween with a height indicated by the double arrow. Space S preferably has a maximum height between an underside **32**U of displacement portion **32** and the surface of the tibia in a range of about 5-25 mm, or more typically about 10-20 mm, in order to accommodate the fat pad and other tissues beneath the displacement portion **32**. Displacement portion **32** has a supporting section **32**B, as described above, that sits in engagement with the tibia in the space between the tibial tuberosity TT and the caudal edge of the fat pad, thereby supporting displacement portion **32**. Height (H), the perpendicular distance between the bone engaging surface **326** of supporting section **32**B and the apogee of bearing surface **34**, as also described above, is shown in FIG. **9**D.

To fit displacement portion **32** within the available space, with reference again to FIG. **9**A, supporting section **32**B preferably extends in the cranial-caudal direction a distance (SS) of no more than about 20 mm, usually being about 5-15 mm, more preferably about 8-12 mm. The cranial end **32**C of displacement portion **32** preferably extends a distance (CE) of about 5-30 mm, typically about 10-25 mm, or more typically about 15-22 mm in the cranial direction from the upper (cranial) extent of supporting section **32**B, which lies against the tibia approximately at dimension line (DL) in FIG. **9**A The concave shape of the posterior side of displacement portion **32** causes its lateral margin **33** to extend around the lateral side of the tibia (if the fixation portion of the implant is mounted on the medial side). In some embodiments, for example as shown in FIG. **9**B, lateral margin **33** may be configured to contact the tibia to provide additional support for the displacement portion and bearing surface in resisting forces applied by the patellar tendon, particularly at high flexion angles. An additional embodiment may have an additional fixation portion on the lateral end of the implant as shown in FIG. **9**C, to provide additional support and stabilization for the implant.

FIG. **10** illustrates an embodiment of the present invention, such as implant **30** described above, after implantation

on the tibia. In this embodiment, implant **30** also employs an extended fixation portion **38**A for enhanced torque resistance as described in more detail below. Fixation portion **38**A may have an extension portion that wraps around either the anterior or posterior side of the tibia, or both, to further stabilize the implant. Multiple screw holes **39** and bone screws **31** are used as dictated by patient anatomy and clinical factors such as condition of the bone.

Placement and fixation of an implant according to embodiments of the present invention can often be accomplished through a single surgical incision adjacent the patient's knee. The implant is then placed through the incision with the displacement portion inserted under the patellar tendon cranially with respect to its attachment point to the tibia at the tibial tuberosity. A therapeutic location that is a target area for placement of the displacement portion includes the caudal pocket below the infrapatellar fat pad containing the infrapatellar bursa (B). Reference letter (B) is provided in FIG. **10** to identify the target area, but the bursa itself is not shown because in some situations it may be necessary to remove part or all of the bursa to accommodate the implant. However, unlike the articular capsule or the infrapatellar fat pad, there are not significant potential negative indications associated with removal or dissection of the infrapatellar bursa.

Placement of the implant as shown for example in FIG. **10**, allows the implant to be placed and fixed through a single incision without penetrating the capsule (C) or dissecting the infrapatellar fat pad (FP) or separating it from its attachment along the posterior of the patellar tendon (PT). Of course, depending on the shape and size of the implant as clinically determined by the surgeon, it may be necessary to push on and somewhat reposition the fat pad as indicated in FIG. **10** as compared to FIG. **1**. Also, as previously described, the smooth, curved shape of the bearing surface **34** and displacement portion **32** moves the patella anteriorly and away from the femur while limiting the amount of movement caudally, thus reducing or avoiding a Baja effect. The shape of implant **30** also effectively avoids and preserves the natural attachment point of the patellar tendon (PT) to the tibia at the tibial tuberosity (TT).

FIG. **10** also further illustrates how the shape of the spanning section **36** and displacement portion **32** provides a cantilevered bearing surface **34** to define space (S) under the implant to accommodate the fat pad and its attachment to the side of the tibia. The cantilevered portion of the implant may be configured to deflect under high loading conditions to reduce strain on the tendon. Such deflection may be engineered into the implant by selection of shape, thickness and material so as to allow the implant to flex, or more active means such as springs or hydraulic cylinders may be used. In further alternatives, bearing surfaces of implants according to embodiments of the invention may include resilient elements such as fluid filled pillows and/or pressure control volumes utilizing check or relief valve systems.

FIGS. **11**A and **11**B illustrate further alternative embodiments employing supplemental support and fixation elements **50** and **54**. Implants **40**A and **40**B each include fixation portion **42** with fixation means such as bone screw holes **43**, spanning section **44** and displacement portion **46** with bearing surface **48**, all as previously described. Positioned at the end of displacement portion **46** on implant **40**A is supplemental support and fixation tab member **50** with at least one bone screw hole **52**. In some embodiments, implant **40**A may be generally shaped in a manner similar to implant **30** of FIG. **9**B, with tab member **50** disposed at the lateral margin **33** of the implant having a bone engaging surface in contact with the tibia. In other embodiments, the shape may be generally reversed such that tab member **50** would be disposed at a medial margin of the implant displacement portion. In a further embodiment shown in FIG. **11**C, tab member **50** has no bone screw hole, but simply provides additional surface area resting against the tibial surface to stabilize the device and to more widely distribute the pressure of the device due to the force of the patellar tendon against the device.

The position of tab member **50** with respect to fixation portion **42** may necessitate a second surgical incision site when placing implant **40**A. In order to provide supplemental fixation and support means without necessitating a second incision site, means such as shown in FIG. **11**B for implant **40**B may be alternatively employed. In this embodiment, displacement portion extension **56** extends the displacement portion in a caudal direction around the lateral side of the tibia (if the fixation portion **42** is mounted to the medial side of the tibia). Supplemental support and fixation tab **54** is disposed at the caudal and/or lateral margin of the extended displacement portion and provided with at least one fixation hole **57**. To allow for placement and fixation from a single incision site, fixation hole **57** is configured to accommodate fixation rod **58** and is aligned with a corresponding fixation hole **57** in fixation portion **42**. Fixation rod **58** may comprise a threaded rod or elongated bone screw, and fixation hole **57** may be threaded so as to receive the threaded tip of the fixation rod. In an alternative embodiment, fixation rod **58** may be threaded over its entire length with a pointed distal end and a bone screw head at the proximal end adapted to receive a torqueing tool such as a hex driver.

Placement of an embodiment such as implant **40**B is achieved by positioning the fixation portion on one side of the tibial tuberosity with the extended displacement portion **56** extending around the attachment of the patellar tendon to the tibia and back down caudally on the opposite side of the tibial tuberosity. With fixation holes **57** thus aligned on opposite sides of the tibia, fixation rod **58** may be inserted through the same surgical incision and through a portion of the tibia to fix both holes **57** in a single operation. Additional fixation screws may be placed in other holes **43**, again through the same surgical incision. A specialized drill guide might be employed to ensure accurate alignment while drilling the hole.

Depending on patient anatomy and other clinically determined parameters, placement of an implant according to embodiments of the present invention may present a challenge because of the torqueing forces exerted on the displacement portion after insertion under the patellar tendon, even before fixation means, such as bone screws, are secured. Such torqueing forces would tend to lift the fixation portion away from the bone surface to which it was to be affixed. In this situation, a separate fixation base may be employed as shown, for example, in FIGS. **12**A-E. In this alternative embodiment, implant **60** has a fixation portion that comprises a body member fixation portion **62**A and a base member fixation portion **62**B. FIG. **12**A shows the part unassembled before placement of the body member fixation portion **62**A, and FIG. **12**B shows the assembled parts as they may appear after placement.

As shown in FIGS. **12**A and **12**B, implant **60** also includes spanning section **66** and displacement portion **68** with bearing surface **69** generally as previously described. In one embodiment, screw holes **63**, configured to receive bone screws **64**, are provided only in base member fixation portion **62**B. In a further alternative embodiment, illustrated only in FIG. **12**A, additional fixation screw holes **63**A may

be provided in both the base member and body member fixation portions and positioned so that the holes align when the body member is received in the base member. In another alternative embodiment, bone screw access holes **63**B may be provided as discussed further below. Access holes **63**B are shown in FIG. **12**A in dashed lines as optional features.

Body member fixation portion **62**A and base member fixation portion **62**B are provided with complementary, mating shapes to permit them to be securely fitted together. Persons of ordinary skill in the art may select from various complementary shapes, one example of which is shown in FIGS. **12**C and **12**D, which are end views at lines C-C and D-D, respectively, in FIG. **12**A. In this exemplary embodiment, base member fixation portion **62**B defines a channel **70** with retaining edge **72** that extends therearound. The complementary shape of body member fixation portion **62**A is provided by guide channel **74**, which in this exemplary embodiment extends around the caudal end and onto both sides of the body member fixation portion **62**A. In other embodiments, separate mating features may be provided only on the sides, not extending around the caudal end of the implant.

The two-piece design of an embodiment such as implant **60** permits the base member fixation portion **62**B to be first secured at a selected location without an eccentric or torqueing forces applied by the target tissue through the displacement portion **68**. Fixation means such as holes **63** and bone screws **64** may be used to secure the base member fixation portion **62**B. Once proper placement is confirmed, displacement portion **68** may be inserted under the target tissue, such as the patellar tendon, and then base member fixation portion **62**A inserted into base member fixation portion **62**B with a relatively straightforward sliding action as indicated by the arrow in FIG. **12**A to provide a combined implant generally as shown in FIG. **12**B. Screw holes **63** and screws **64** are shown in phantom lines in FIG. **12**B because they are covered by body member fixation portion **62**A. For this reason screws **64** preferably are low profile screws with flat heads to avoid interference with the body member when inserted into the base member. Channel **74** is also shown in phantom lines because it is received behind edge **72**.

Various locking means for securing the body member to the base member are possible. One such locking means embodiment is schematically illustrated in FIG. **12**E. In this illustrative embodiment, inter-engaging teeth **76**A and **76**B are provided on the facing surfaces, respectively, of the body member channel **74** and the base member retaining edge **72**. When body member is inserted into the base member as indicated by the arrow in FIG. **12**E, the inter-engaging teeth act in a ratchet-like manner, permitting insertion but preventing removal. In some embodiments, the teeth may themselves be formed with resiliency to permit insertion. In other embodiments, the teeth may be relatively short with less resiliency to permit insertion provided by elastic deformation of base member fixation portion **62**B and retaining edge **72**. For even greater fixation security, after the body member is fully received in the base member, additional bone screws may be inserted through optional, additional fixation screw holes **63**A, which become aligned as described above.

It will also be appreciated by persons of skill in the art, that inter-engaging teeth or other ratchet-type locking means may be difficult to disengage if it becomes necessary to remove or reposition the base member during the initial implant procedure or a later intervention. Disengagement may be achieved, for example, by deformation of base member fixation portion **62**B and retaining edge **72**. In one alternative, bone screw access holes **63**B may be provided in body member fixation portion **62**A as shown in FIG. **12**A. Access holes **63**B are positioned to align with bone screw holes **63** in base member fixation portion **62**B when the body member is received in the base member after implantation. Using access holes **63**B, bone screws **64** may be removed without separating the body member from the base member.

In another alternative embodiment, inter-engaging or ratchet-type locking means is not provided. Instead, locking means may be provided by one or more additional fixation screw holes **63**A. In such an embodiment, body member fixation portion **62**A may be freely inserted and removed from base member fixation portion **62**B once the base member is installed. The complementary shape of the mating parts as described initially carries the torqueing force of the target tissue acting on displacement portion **68** and then the two members are locked together using bone screws through one or more additional fixation screw holes **63**A. Bone screw access holes **63**B also may be included as desired to provide further removal options.

FIG. **12**F shows an additional alternative body member-base member geometry, with a curved interface between the parts which allows adjustment for any variation in the angle of the tibial surface against the fixation portion. This allows the body member **69** to be positioned so that the posterior edge of the displacement section rests firmly against the tibia as the fixation screws are tightened.

As mentioned above, torqueing and other complex forces applied to the fixation portion through the target tissue acting on the displacement portion may be significant. In order to better resist such forces various supplemental fixation and support embodiments may be provided. Two such exemplary embodiments have been described above in connection with FIGS. **11**A and **11**B. Additional exemplary embodiments are shown in FIGS. **13**A-E. Implants **80**A-E of FIGS. **13**A-E each include fixation portion **82** with screw holes **83**, spanning section **84** and displacement portion **86** with bearing surface **88** generally as previously described. In addition to these basic structures, implant **80**A may include extension portions extending from fixation portion **82** in a direction generally transverse to that of fixation portion **82**. For example, as shown in FIG. **13**A, an extension portion **90**A may be configured to extend generally in the same direction as the displacement portion, e.g., if the fixation portion **82** is mounted on the lateral side of the tibia, in a medial direction (or angled medially and caudally), across the anterior surface of the tibia transverse to the longitudinal axis of fixation portion **82**, but caudally of the tibial tuberosity. In another alternative, as shown in FIG. **13**B, implant **80**B includes extended fixation portion **90**B, which extends in a direction opposite from the displacement portion **86**, e.g. laterally, or laterally and caudally, relative to fixation portion **82** so as to extend around the lateral side of the tibia. In another example, if the fixation portion **82** is mounted to the medial side, extended fixation portion **90**B may be configured to extend posteriorly further around the medial and/or posterior side of the tibia (if the fixation portion **82** is mounted to the medial side). Extended fixation portions **90**A and **90**B create a wider base for fixation portion **82** and thus provide greater resistance to torqueing forces as described. Extended fixation portions **90**A and **90**B generally will be configured and dimensioned to match the shape of the tibia in the area of contact.

An extended fixation portion configured and positioned as extended fixation portion **90**A will help to resist torqueing applied to the displacement portion **86** by creating a greater surface bearing against the bone at a greater distance from

the center of rotation of the torqueing force, which will lie approximately along a centerline of fixation portion **82**. An extended fixation portion configured and positioned as extended fixation portion **90**B will help to resist torqueing force applied to the displacement portion **86** by creating a greater lever arm through which a bone screw in fixation holes **83** may act to resist the torqueing force. In some situations it may be desirable to utilize both extended fixation portions **90**A and **90**B to achieve the benefits of both approaches. FIG. **13**C shows exemplary implant **80**C employing both laterally- and medially-extended fixation portions **90**A, **90**B on one device.

Depending on patient anatomy, it may be desirable to provide a fixation portion that wraps farther around the tibia. In such situations, a split or bifurcated fixation portion **92** may be employed such as shown with implant **80**D in the exemplary embodiment of FIG. **13**D. In this embodiment, split fixation portion **92** forms two fixation arms **92**A and **92**B at its caudal end, one extending laterally and posteriorly, and a second extending medially and anteriorly, that can be configured to wrap around the tibia in opposing directions to the extent appropriate for the patient anatomy and clinical situation presented. These fixation arms **92**A, **92**B can be oriented transverse to longitudinal axis of fixation portion **92** to extend primarily in the medial-lateral direction, or angled caudally as wells as medially or laterally. Alternatively, a single arm **92**A or **92**B may be employed in a manner similar to the exemplary embodiments of FIGS. **13**A and **13**B employing single extended fixation portions **90**A or **90**B. In addition, the caudal ends of fixation arms **92**A, **92**B may have holes configured to receive a rod or screw extending through one fixation arm **92**A and through the tibia to the other fixation arm **92**B.

Again, depending on patient anatomy, it also may be desirable to provide differently shaped bone facing fixation surfaces for fixation portion **82**. Alternatives include fixed protrusions **94** and adjustable protrusions **96** as illustrated in FIG. **13**E. Such protrusions allow the fixation portion **82** to contact the bone at discreet locations to accommodate variability in the contour of the bone surface. Fixed protrusions may be ground to a desired height and shape according to the anatomy of each patient to provide further patient specific adaptability. Adjustable protrusions may be provided with an adjustment mechanism **98**, such as a threaded member accessible at the outer surface of fixation portion **82** and rotatable to move adjustable protrusions **96** between an inner position and an outer position (shown in dashed lines in FIG. **13**E) to adjust the distance the protrusion extends from the fixation portion **32**. Alternatively or additionally, fixed or adjustable protrusions may be provided on the bone-facing side of the displacement portion such that it contacts the bone at discrete locations, accommodating variations in shape of the bone surface on the cranial side of the tibial tuberosity where the displacement portion extends under the patellar tendon.

The present disclosure contains multiple alternative embodiments and multiple alternative features within each disclosed embodiments. As will be apparent to persons of ordinary skill in the art based on the teachings herein contained, different features may be employed with embodiments other than those on which they are shown in the drawings for purposes of illustration. Given the number of possible combinations, it is not possible within a concise disclosure to separately illustrate each combination of features as would be understood by those skilled in the art. As non-limiting examples, each of the different supplemental fixation or support means shown in FIG. **11**A or **11**B, the fixation base member shown in FIGS. **12**A-E, and/or the different fixation portion shapes shown in FIGS. **13**A-**13**E may be used together in different combinations or individually with each different implant herein.

FIGS. **14**A and **14**B depict further exemplary embodiments of implants **400**A and **400**B, respectively, also for treating patellofemoral osteoarthritis and/or patellar maltracking, but with femorally mounted implants as shown. As with other embodiments disclosed herein, implants **400**A and **400**B each have a fixation portion **412** including one or more holes **415** for receiving screws, or other fixation means for anchoring the implant to bone. Fixation portion **412** is generally straight and elongated, being configured for positioning in general alignment with the femoral shaft on the lateral, medial or anterior-medial/lateral side of the femur, cranially with respect to the patella. Holes **415** may be positioned in approximate alignment with a longitudinal centerline of fixation portion **412** as shown, however additional holes may be included for added fixation security, similar to embodiments shown, inter alia, FIG. **10** or **13**A-D. Preferably fixation portion **412** is configured to be mounted to the femur outside the joint capsule, cranially with respect to the tendons, ligaments and other tissues that form the capsule.

Displacement portion **414**, is configured and dimensioned to be positioned under the quadriceps tendon caudally separated from the insertion point of the tendon in the quadriceps muscle and cranially with respect to its attachment point to the patella, with the entire displacement portion **414** preferably being disposed entirely outside the joint capsule. Thus, for a medially placed implant displacement portion will also extend laterally across an anterior portion of the femur. Likewise, a laterally placed device will have a displacement portion **414** that also extends medially across an anterior portion of the femur. The displacement portion **414** is configured to atraumatically engage the quadriceps tendon and displace it anteriorly relative to the femur, thus increasing space in the patellofemoral area. The displacement portion **414** has a width in the lateral-medial direction selected to accommodate the full width of the quadriceps tendon so that the tendon remains engaged along its entire width as it slides on the displacement portion. Displacement portion **414** has a length in the caudal-cranial direction selected so that it does not interfere with the patella. Displacement portion **414** preferably has a convex curvature on bearing surface **418**, which engages the tendon. In general, the displacement portion and, in particular the bearing surface of the displacement portion, will be free of holes or other fixation means, with configuration similar to the bearing surfaces in other described embodiments.

As with tibial mounted embodiments, the displacement portion **414** and/or bearing surface may have a curvature which provides a constant displacement of the tissue throughout the range of motion of the joint, or configured to vary the displacement at different points throughout the range of motion. The curvature may be entirely or partially spherical, elliptical, parabolic, logarithmic spiral, or other curvature or combination thereof. In preferred embodiments the displacement portion **414** is configured such that a cranial aspect of bearing surface **418** slopes or curves gradually away from the femur as it extends in the caudal direction to provide gradually increasing displacement of the tendon.

A spanning section **416** interconnects fixation portion **412** and displacement portion **414**. Spanning section **416**, is previously described to appropriately position the displacement portion with respect to the fixation portion and soft and

bony tissues in the area of treatment. As with other embodiments, displacement of the target tissue can be altered by changing the length, curvature and angle of the spanning section among other features. Implant **400**A (FIG. **14**A) may also include a cantilevered portion **420** of displacement portion **414** which has an undercut surface that is spaced apart from the underlying femoral surface. As with other described embodiments, cantilevered portion **420** creates a space (S) between the implant and the bone to accommodate soft tissue structures as needed. Cantilevered portion **420** also extends the displacement portion **414** in the caudal direction toward the patella to optimize displacement while minimizing interference with the joint capsule and other soft tissues. Alternatively, implant **400**B, shown in FIG. **14**B, may be configured without a cantilevered portion such that substantially all of the bearing surface **418** overlies and is supported by portions of the displacement portion **414** that engage the femur.

Implants **400**A, **400**B may optionally include various other features described above in connection with tibially mounted embodiments. For example, implants **400**A and **400**B may include a supporting section extending from a cranial part of the underside of the displacement portion into and merging with the fixation portion as described above in connection with tibially mounted embodiments. The configuration of a supporting section in these embodiments will, however, be generally inverted to accommodate fixation on the femur cranially with respect to the patella, as opposed to, on the tibia, caudally with respect to the patella. Implants **400**A, **400**B may alternatively have a tab or extension portion extending cranially, medially, and/or posteriorly from the displacement portion **414** on the opposite side from the fixation portion **412** which can engage the femur to provide additional support for the displacement portion **414**. As with the embodiments shown in FIGS. **11**A and **11**C, such tab or extension may include a hole through which a bone screw may be inserted into the bone, or a hole for receiving a rod or screw extending from fixation portion **412** through the femur.

In general, implants according to embodiments of the present invention may be positioned and fixed using well-known instrumentation that is used for other orthopedic implant procedures. However, because of the unique position and seating of embodiments of the present invention, a specially shaped curved file as shown in FIGS. **15**A and **15**B may be useful for preparing the bone surface at the implant location, particularly for tibially mounted implants. Curved file **500** comprises a shaft **502** with a handle **504** at a proximal end and a curved file element **506** at the opposite, distal end. File element **506**, preferably made of a metal suitable for filing bone, extends in a transverse direction from shaft **502** and has a lower surface **506**A and an upper surface **506**B, one or both of which have grooves, knurling, points, bumps, or other features configured to file the bone surface to give it a suitable shape for receiving the implants of the invention. File element **506** is preferably curved about a second axis extending in a direction transverse to shaft **502** longitudinal axis in an anterior-posterior direction, giving file element **506** a convex cranial side **507** and a concave caudal side **509**. Upper and lower surfaces **506**A, **506**B are disposed at least partially in respective planes which are intersected by the second axis. In addition, lower and/or upper surfaces **506**A, **506**B may have a curvature about a third axis parallel to the longitudinal axis of shaft **502**. This latter curvature may have various shapes, e.g. generally matching the curvature of the anterior surface of the tibia in the region just cranial to the tuberosity where the implant will be fixed, or a different curvature as is suitable to provide a stable base for the implant. Further, either or both the convex cranial side **507** or concave caudal side **509** may have grooves or other features to facilitate filing the bone with these surfaces. Moreover, the lower and/or upper surfaces **506**A, **506**B may have either a convex or concave curvature about an axis transverse to shaft **502** as may be suitable to create the particular shape desired for the bone surface. The file element **506** may be inserted through an incision on the lateral or medial side of the tibia just cranial to the tibial tuberosity such that the file element extends across the anterior tibial surface. File **500** may be drawn back and forth in a cranial-caudal direction (parallel to the tibial shaft), or in a medial-lateral direction, to file down the tibial surface cranially of the tuberosity to the desired shape. It should be noted that in addition to their use in implanting the implants of the invention, the files disclosed herein may be used for other treatments, including bone re-shaping for the treatment of Osgood-Schlatter disease or other diseases.

FIGS. **16-20** illustrate further exemplary implants made according to the teachings of the present disclosure. For example, implant **610** in FIG. **16** is made according to the general teachings of the disclosure and includes, inter alia, fixation portion **612**, displacement portion **614** and spanning section **616**, as well as other features described herein for the various embodiments. Implant **620**, shown in FIG. **17**, includes a fixation portion **622**, displacement portion **624** and spanning section **626**, wherein displacement portion **624** is extended laterally as compared to implant **610** so that the lateral edge **628** of displacement portion **624** may be supported on the tibia, for example on Gerdy's tubercle or adjacent thereto, to provide a supplemental support element. In this regard, implant **620** includes features similar to embodiments shown in FIGS. **9**A-D. Implant **630**, shown in FIG. **18**, also includes a fixation portion **632**, displacement portion **634** and spanning section **636**. Displacement portion **634** has a gradually increased thickness area **638** towards the lateral end in order to increase the tendon displacement at the lateral side. Implant **640**, shown in FIG. **19**, includes fixation portion **642**, displacement portion **644** and spanning section **646**. In this embodiment, displacement portion **644** includes lateral pad **648** at an outer end to provide supplemental support and fixation adjacent the tibial tubercle. In this regard, implant **640** may include features similar to embodiments shown in FIGS. **11**B and **11**C. Additionally, lateral pad **648** may be designed to hook the tibial tubercle. Implant **650**, shown in FIG. **20**, includes fixation portion **652**, displacement portion **654** and spanning section **656**. Fixation portion **652** has a bone engaging surface **658** formed with a convex profile to facilitate positioning along the tibial tuberosity prior to fixation. The convex profile may be in the range of about 10 degrees of convexity.

Exemplary embodiments have been disclosed above and illustrated in the accompanying drawings. It will be understood by those skilled in the art that various changes, omissions and additions may be made to that which is specifically disclosed herein without departing from the spirit and scope of the present invention.

What is claimed is:

1. A prosthesis for treating disorders of the knee in the patellofemoral compartment of the knee, the prosthesis comprising:

a fixation portion configured to be mounted to the tibia at a fixation site proximate the upper tibial extremity and medially or laterally of the tibial tuberosity;

a spanning section configured and dimensioned to extend cranially and laterally or medially from the fixation portion in a direction towards the tibial mid-line; and

a displacement portion having an overall curvature around an axis generally parallel to the tibial shaft when the fixation portion is mounted at the fixation site and configured and dimensioned to (i) extend from the spanning section further laterally or medially under patellar tendon and in engagement therewith, and (ii) displace the patellar tendon anteriorly sufficiently to alter the location, angle or magnitude of forces exerted thereby on the patella so as to achieve a therapeutic effect in patellofemoral compartment of the knee.

2. The prosthesis of claim **1**, wherein the therapeutic effect comprises a reduction of loading on an articular surface in the patellofemoral compartment of the knee.

3. The prosthesis of claim **1**, wherein:

the displacement portion has a base portion configured to engage at least in part an anterior surface of the tibia and a cantilevered portion extending from the base portion to a free end, the cantilevered portion being configured to be spaced apart from the tibia when the base portion is engaging the tibia;

the displacement portion includes a bearing surface configured to atraumatically engage the patellar tendon, the bearing surface being free of holes or other fixation means; and

said base portion and said cantilevered portion e formed with said curvature around a common axis generally parallel to the tibial shaft.

4. The prosthesis of claim **1**, wherein said displacement portion and spanning section are configured and dimensioned in combination to displace the patellar tendon from a pre-treatment anatomical path by displacement distance of more than about 5 mm and less than about 30 mm when the fixation portion is mounted to the tibia.

5. The prosthesis of claim **4**, wherein said displacement portion and spanning section are further configured to position the displacement portion to define a space between at least a part of the displacement portion and the tibial surface.

6. The prosthesis of claim **5**, wherein said displacement portion is configured and dimensioned to form a cantilevered structure with respect to the tibial surface with said space positioned under at least a portion of the cantilevered structure of the displacement portion when the fixation portion is mounted to the tibia.

7. The prosthesis of claim **6**, wherein said space is further defined by a cranially-facing undercut in the displacement portion.

8. The prosthesis of claim **5**, wherein:

the displacement portion has an outer end opposite the spanning section with said outer end including a supplemental support element having a bone engaging surface configured and dimensioned to rest against the tibia to support said displacement portion.

9. The prosthesis of claim **8**, wherein said space is defined in an area between the spanning section and bone engaging surface of the displacement portion outer end.

10. The prosthesis of claim **8**, further comprising a bone fixation element cooperating with said supplemental support element.

11. The prosthesis of claim **10**, wherein said bone fixation element comprises at least one bone screw hole in said supplemental support element.

12. The prosthesis of claim **8**, wherein said displacement portion and supplemental support element lie along a displacement portion axis at an angle of about 80-135 degrees with respect to a fixation portion axis.

13. The prosthesis of claim **8**, wherein the displacement portion outer end extends in a caudal direction, with the displacement portion configured to extend around the tibia to an opposite side of the tibia from the fixation portion.

14. The prosthesis of claim **13**, wherein the supplemental support element includes at least one fixation hole aligned with at least one bone screw hole in the fixation portion, said fixation hole and said bone screw hole configured to receive a single fixation rod extending therethrough.

15. The prosthesis of claim **8**, wherein:

the fixation portion comprises a body member and a separate base member to which the body member may be coupled, said body and base members having complementary, mating shapes to provide a secure coupling of the body member to the base member; and

the separate base member includes plural bone screw holes for fixation to the tibia.

16. The prosthesis of claim **15**, further comprising locking means for securing the fixation portion body member to the fixation portion base member.

17. The prosthesis of claim **1**, wherein:

the fixation portion is disposed at an angle with the spanning section such that with the prosthesis implanted and the displacement portion engaging the patellar tendon, the fixation portion is substantially aligned with the tibial shaft;

the spanning section is configured and dimensioned to avoid contact with the medial edge of the patellar tendon; and

the displacement portion is further configured and dimensioned to lie substantially parallel to the axis of the tibial plateau when the fixation portion is secured medially of the tibial tuberosity with the fixation portion substantially aligned with the tibial shaft.

18. The prosthesis of claim **1**, wherein:

the fixation portion comprises a body member and a separate base member to which the body member may be coupled, said body and base members having complementary, mating shapes to provide a secure coupling of the body member to the base member; and

the separate base member includes plural bone screw holes for fixation to the tibia.

19. The prosthesis of claim **18**, wherein the fixation portion body member includes at least one bone screw access hole positioned to align with a bone screw hole in the fixation portion base member when said body member is fit with the base member.

20. The prosthesis of claim **18**, further comprising locking means for securing the fixation portion body member to the fixation portion base member.

21. The prosthesis of claim **20**, wherein said locking means comprise inter-engaging surfaces on said base and body members.

22. The prosthesis of claim **20**, wherein said locking means comprises at least one bone screw hole extending through both said base and body members.

23. The apparatus of claim **1**, wherein the fixation portion includes alterable protrusions on a bone facing surface, said protrusions being alterable to match bone surface contour at a fixation site.

24. A prosthesis for repositioning a target tissue, the target tissue comprising a connective tissue or muscle relative to a bone on which said target tissue acts, and the prosthesis comprising:

a fixation portion having one or more fixation features configured to receive fixation elements for securing the implant to the bone; and

a displacement portion having a first end connected to the fixation portion and a free end opposite the first end, the displacement portion having a bearing surface configured to atraumatically engage and reposition the target tissue relative to the bone;

wherein the displacement portion has a base portion configured to engage the bone and a cantilevered portion extending from the base portion to the free end, the cantilevered portion being configured to be spaced apart from bone when the base portion is engaging the bone, the base portion and the cantilevered portion each having a curvature formed around a common axis parallel to a longitudinal axis of the bone when the fixation portion is secured thereto.

25. The implant of claim **24**, wherein the displacement portion is at least partially ramp-shaped such that, when implanted, a lower part of the displacement portion has a first height relative to the bone surface and an upper part of the displacement portion has a second greater height relative to the bone surface, the ramp-shaped portion facing in a direction generally away from the free end.

26. The implant of claim **24**, wherein the displacement portion is connected to the fixation portion at an end opposite the free end by a spanning section.

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